Protocol-based reasoning in diabetic patient management

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Abstract

We propose a system for teleconsultation in Insulin Dependent Diabetes Mellitus (IDDM) management, accessible through the use of the net. The system is able to collect monitoring data, to analyze them through a set of tools, and to suggest a therapy adjustment in order to tackle the identified metabolic problems and to fit the patient’s needs. The therapy revision has been implemented through the Episodic Skeletal Planning Methodi, it generates an advice and employs it to modify the current therapeutic protocol, presenting to the physician a set of feasible solutions, among which she can choose the new one. © 1999 Elsevier Science Ireland Ltd. All rights reserved.

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1. Introduction

It is nowadays well-known that the incidence and severity of later-life complications resulting from Insulin Dependent Diabetes Mellitus (IDDM) can be reduced if patients receive a treatment leading to good glycemic control, by maintaining a careful balance between diet, insulin therapy and physical exercise [1]. These goals may be achieved if patients undergo Intensive Insulin Therapy (IIT), which involves three to four Blood Glucose Level (BGL) measurements a day or continuous sub-cutaneous injections. IIT has serious drawbacks, like the increase in risk of severe hypoglycemic events and the increase in treatment costs, due to the need for more frequent home assistance and continuous education of patients. The benefits and prob-
lems of IIT motivate a growing attention towards information technologies for improving diabetic patients' care. Since the early '80s, many decision support systems for IDDM patient management have been proposed. An extensive review of the application of computer systems in diabetes care can be found in Lehmann and Deutsch [2]. For the purposes of this paper, following Deutsch et al. [3], we will classify these systems into two categories: day by day advisory systems and visit by visit systems.

Day by day advisory systems are mainly devoted to supply therapeutic advice to patients and physicians during the every day self-management of the disease. Algorithms for insulin dose adjustments implemented into hand-held devices [4–7] can be found in this category, together with more complex systems which provide optimal or suboptimal insulin dose modifications on the basis of a model of the diabetic patients’ behavior [8,9].

Visit by visit systems are devoted to assist physicians in interpreting the time series coming from home monitoring data and hence in revising the therapeutic protocol that the patient is following. Several examples have been proposed to this end [10–12].

The most recent implementations try to overcome the weakness of traditional expert systems [13] that used medical knowledge out of its natural context, without taking into account the real features and needs of the health-care environment. Visit by visit systems are aimed at improving the overall treatment quality, and integrate the data management, the data interpretation and the decision support task in a uniform way. An example of these integrated systems is UTOPIA/DIAMOND [12], that couples data-base and decision support in the same tool.

The information age has now enabled a third class of decision support systems, that are aimed at combining the advantages of both day-by-day and visit-by-visit systems: they are distributed information systems (DIS), that, thanks to their distributed nature, provide advice to both patients and physicians through a network connecting the patients' house and the clinic. Examples of these integrated frameworks are the DIABTEL system [14] and the HUMALINK system [15].

Although the use of DIS in Diabetes care needs to be tested in prospective studies, the preliminary results obtained, together with the continuous improvement of the available telecommunication infrastructure, pushes towards the definition of DIS that are more capable of capturing the complexity of IDDM patients management. To this purpose, the EU-funded TIDDM project [16] proposes a DIS based on a two-level hierarchical control architecture based on two distinct and cooperating modules: a patient unit (PU) and a medical unit (MU). While the MU assists the physician in the definition of the basal insulin regimen and diet through a periodic evaluation of the patient's data, the PU helps the patient collecting data, both manually and automatically from a reflectometer, and transferring them from her home to the clinic, moreover it supports the patients in their self-monitoring activity, by suggesting the insulin dosage adjustments, if needed. From a decision-support perspective, the MU integrates a visit-by-visit assistance for the physician with the possibility of providing telegenic care to patients, via the telecommunication link between hospital and patients' house. On the other hand, the PU gives day-by-day support to the patients, allowing for intelligent alarming and teleconsultation. The details of the architecture are described elsewhere [17,18].

In this paper we will concentrate on the decision support functionalities implemented in the MU, whose goals are basically to provide physicians with a flexible instrument
for managing a large number of patients in a semi-automatic fashion, through an intelligent handling and customization of the different therapeutic protocols available.

In Section 2 we will briefly state the problem of revising therapy in IDDM monitoring. Section 3 will describe the protocol-based reasoning process exploited by the MU, while Section 4 will show an example of the reasoning capabilities of the system, as implemented within the MU on a real clinical case.

2. T-IDDM monitoring of an IDDM patient

In current medical practice, IDDM patients report the results of their self-monitoring activities in hand-written diaries. The diary is revised and a new therapeutic protocol is defined only when a patient undergoes the periodic control visit.

Within the T-IDDM system, we aim at providing a telemedicine service that should improve the quality and efficiency of the overall monitoring/therapy revision process. Patients collect metabolic data together with insulin and food intake information every day, and store them in the PU data base. Whenever a problem occurs, they can send an alarm and the data to the MU to get a quick response from the physician, otherwise all the information will be sent every 7–10 days. The physician will receive the data, and analyze them through the tools provided by the MU. She will get further information from physical examination when the periodic visit takes place (every 2 months or even less frequently, if the patient has a good metabolic control). As patients' monitoring data could be analyzed more than once every 2 months, a therapy adjustment could be immediately suggested in order to solve possible alterations, thus avoiding more serious complications. The quality of the IDDM patients monitoring should be hence improved through a better metabolic control, with a quicker reaction against potential dangerous situations, the efficiency of the overall monitoring service should be increased by reducing the accesses to the hospital as well as by optimizing the patients’ visit schedule.

As described in [19–21], the decision support functionalities of the MU are performed in three steps: (i) high-level metabolic parameters are extracted from the home monitoring data (intelligent data analysis); (ii) the state of the patient is evaluated on the basis of descriptors derived in the previous step [21]; and (iii) a protocol revision is then suggested, if needed. Therapy revision strategy will be presented in detail in Section 3, in this section we will briefly describe the outcomes of phases (i) and (ii).

2.1. Data analysis

The data collected through home-monitoring contain limited information. The typical PU data set stores BGL measurements, insulin dosages, hypoglycemic events, presence of ketone in the urine and modifications of diet and physical exercise, with respect to the typical patients’ life-style. All this data are time-stamped, and acquired several times (from three to four) a day.

In order to allow a proper interpretation of the data, the 24 h daily period is subdivided into a set of consecutive non-overlapping time slices: breakfast; midmorning; lunch; midafternoon; dinner; bedtime; and nighttime. These time slices are generated on the basis of the information about the patient’s life-style, in particular meal times. Each datum is hence associated to a given time slice.

The MU exploits the information coming from the PU through a set of tools to visualize and to analyze collected data. The physician is allowed to inspect all the available
time series, that is BGL, glycosuria, ketonuria, HbAlc and insulin intakes, or to restrict the set of information to be plotted to data belonging to a single time slice, or to a given time interval from the beginning of the monitoring period. Moreover, a set of statistical methods have been implemented, such as the extraction of the daily average value of BGL, the daily insulin requirement, and the number of serious hypoglycemic events in a given period of time.

The MU also exploits some data characteristics derived by grouping them into series of abstract episodes. In particular an abstract description of the course of longitudinal data is obtained through the temporal abstractions (TA) technique.

The basic principle of TA methods is to move from a time-point to an interval-based representation of the data. Given a sequence of time stamped data (events), the adjacent observations which follow meaningful patterns are aggregated into intervals (episodes). In particular, an ontology which distinguishes two main classes of abstractions has been defined, BASIC abstractions for detecting predefined patterns in a univariate time series, and COMPLEX abstractions, for discovering specific temporal relationships between episodes as well as for analyzing multivariate patterns [20].

In particular, BASIC abstractions extract STATES (e.g. low, normal, high values) or TRENDS (increase, decrease or stationarity patterns) from a uni-dimensional time series. COMPLEX abstractions search for specific temporal relationships between episodes which can be generated from a basic abstraction or from other complex abstractions. The relation between intervals can be any of the temporal relations defined by Allen [22]. This kind of TA can be exploited to extract multidimensional patterns or to detect uni-dimensional patterns of complex shapes. Some examples of the use of both BASIC and COMPLEX abstractions are reported in [18].

The reasoning activity of the MU is based on a careful analysis of STATE abstractions. When detecting STATE patterns in time series of numerical variables, a preliminary qualitative abstraction is carried out [20]. The mapping between the qualitative abstractions and the quantitative levels of each numerical variable depends on the time slice and on the specific patient’s characteristics. For example, the BGL normal range is wider in the morning than around lunch, and it is wider in pediatric patients than in adult ones. Then, the BGL state abstractions are derived, moving from the original time scale to a new scale obtained from the sequence of relevant patterns detected in the data.

After having identified the most significant episodes, the Blood Glucose-Modal Day (BG-MD) can be extracted. It represents a characteristic daily BGL pattern that summarizes the typical patient’s response to the therapy in a specific monitoring period, it is usually derived as the collection of the most probable BGL qualitative level in each time slice. The BG-MD is used to evaluate the protocol performance over the selected time interval, even when the information is poor (e.g. data on meals missing). Several approaches for extracting the BG-MD have been presented in the literature, from simple statistics to time series analysis [23,3].

In our approach we derive the BG-MD by calculating the marginal probability distribution of the BGL STATE abstractions. In particular, we apply a Bayesian method described in [24] that is able to explicitly take into account the presence of missing data.

Five BGL state TAs are considered, Severe hypoglycemia, Hypoglycemia, Normoglycemia, Hyperglycemia, Severe hyperglycemia. Before starting data collection in a given period we may assign a prior probabil-
ity to the occurrence of each state TA equal to $1/5$. After a certain monitoring period of $N$ days, we collect $D$ measurements, while the remaining $M = N - D$ data are missing. The posterior probability bounds of the occurrence of a generic $k$-th of the five levels, given by difference between the upper ($p_{\text{sup}}$) and the lower ($p_{\text{inf}}$) probability bound, can be derived as:

$$p_{\text{inf}} = \frac{1 + d_k}{5 + N}$$

$$p_{\text{sup}} = \frac{1 + d_k + M}{5 + N}$$

where $d_k$ is the number of occurrences of the $k$-th level in the monitoring period.

The difference between $p_{\text{sup}}$ and $p_{\text{inf}}$ is proportional to the number of missing data and is denoted as the ignorance in the monitoring period.

As the monitoring process proceeds, the bounds on the probabilities are updated. At any time we obtain, for each time slice, an interval probability distribution over the BGL state abstractions. The modal day is extracted by taking the BGL states with the highest $p_{\text{inf}}$ in each time slice.

By using the same procedure it is possible to extract the posterior distribution for each monitoring variable. For example, useful indicators are given by the glycosuria and insulin MD.

Once the modal days have been derived, the MU is ready to carry out the protocol-based reasoning task that will be described in the next section.

3. Protocol-based reasoning

In IDDM management the physician must handle the complex task of revising and assigning therapeutic protocols to a (usually) large number of patients, according with the terminology adopted by physicians, we define a therapeutic protocol as a collection of four plans, regarding insulin injections, diet, physical exercise and control law (see next section for details).

In a system for automatic protocol revision, this reasoning activity can be implemented through the Episodic Skeletal Planning Method (ESPM) [25]. ESPM has been designed for domains with time-varying data, and in which actions have a time duration [26]. It has been successfully used in a number of medical applications, like T-HELPER [27]. The ESPM assumes the existence of a skeletal plan, (in the IDDM context, a therapeutic protocol), which involves a set of constituent subplans that are each more detailed than the abstract one (e.g. the insulin plan with the prescribed dosages). Subplans attributes have to be specified at a particular time, depending on the current clinical situation and on additional domain knowledge. The goal of our implementation of ESPM is to provide the patients with a protocol able to solve their metabolic problems, by revising and adjusting that they were following since the latest revision. The method is said to be episodic as it is invoked several times: in fact, therapy is revised at least at every patient’s visit, on the basis of the monitoring data, and possibly also at additional time instants, through teleconsultation.

Every time, the planner analyses patient’s data and the therapeutic actions that are still in progress, and suggests an appropriate therapy by refining an abstract, skeletal plan. The ESPM application leads to the full specification of a therapeutic protocol to be applied to the patient at hand, in the current period of time. In our system, the ESPM is structured in two subtasks: (1) identifying problems; and (2) modifying protocols.
Step (1). Identifies the features of the current situation that might require a modification in the therapeutic approach. This task is executed by first summarizing the indicators derived in the data analysis phase, as was described in the previous section, by calculating the BGL, glycosuria and insulin MD. They then trigger a rule-based reasoning system able to extract the relevant problems (e.g. presence of hyperglycemia or hypoglycemia in at least one time slice of the BG-MD) in the monitoring period.

Step (2). Aims at modifying the current protocol in order to tackle the identified problems.

In the following sections, we will focus our attention mainly on Step (2) of our implementation of the ESPM.

3.1. The protocol ontology

The therapeutic protocols defined in the ontology we developed (see Fig. 1) are the skeletal plans to which ESPM is applied, they just depict the generic structure of a therapeutic protocol, but the values of the attributes of the planning entities (i.e. the insulin doses or the caloric intake) are not specified at this level, and will be calculated by developing the reasoning process in any specific case. A protocol can be hierarchically decomposed into a set of four plans, summarizing the different actions to be carried out.

- Insulin plan: it indicates the number of insulin units to be injected daily (distinguishing regular, NPH and eventually premixed insulin), and their distribution at the different time slices of the day.
- Diet plan: it defines the suggested caloric intakes and their distribution among lipids, proteins and carbohydrates over meals and snacks.
- Exercise plan (optional): it indicates how much the regular insulin dose should be reduced after some physical exercise.
- Control law: it defines the insulin requirement and the diet adjustments on the basis of the patient’s age, weight, and blood glucose measurements just before injections.

The diet plan, the exercise plan and the control law have to be intended as ‘adjustments’ of the prescribed therapy, directly applicable by the patients in dependence of their health status and of occasional life-style modifications. Only if the symptoms persist, a real therapeutic revision will be required, on such situations, the automatic reasoner will be invoked, and will produce suggestions regarding the insulin plan.

At a deeper level of detail, an insulin plan is defined by a set of attributes, that refer to the insulin intake at each time slice. The time slices in which insulin can be injected are five: the three meal time slices (breakfast, lunch and dinner), bedtime and midafternoon. According to the distribution of insulin intake over the day, three classes of insulin plans can be identified:

- The two injection plans, in which insulin is given only at breakfast and at dinner.
- The three injection plans, in which an extra dose of regular insulin is inserted at lunch or at midafternoon.
The four injection plans, in which every meal is compensated by insulin, and an extra dose is given at bedtime, to avoid hyperglycemia at night. Below is shown an example of a three injection insulin plan.

SAMPLE_INSULIN_PLAN
CREATION_TIME '10-16-1997 11:54:53'
AUTHOR 'Dr. Lorini'
PATIENT_ID 1
INJECTIONS_NUMBER 3
BREAKFAST_NPH 0.6
BREAKFAST_PREMIXED 0
BREAKFAST_REGULAR 0.03
LUNCH_NPH 0
LUNCH_PREMIXED 0
LUNCH_REGULAR 0.1
MIDAFTERNOON_NPH 0
MIDAFTERNOON_REGULAR 0
MIDAFTERNOON--PREMIXED 0
MIDAFTERNOON--REGULAR 0
DINNER_NPH 0.24
DINNER_PREMIXED 0
DINNER_REGULAR 0.03
BEDTIME_NPH 0
BEDTIME_PREMIXED 0
BEDTIME_REGULAR 0
REGULAR_INSULIN_TYPE 'Actrapid'
NPH_INSULIN_TYPE 'Monotard'
INJECTION_SITE 'Arm'

The reasoner first proposes its own solution to the metabolic alterations, by fully specifying the attributes of a skeletal plan, suitable for the patient's life style. Then, it identifies the additional library protocols that could face the metabolic problems, and lists them as alternative solutions to its first response. Therefore the physician can choose among a set of suggestions, listed together with an indication of their degree of suitability, deduced from their differences from the protocol adopted in the previous period.

3.2. Situation-based revision

The therapy advisor is implemented through a rule-based system, whose tasks are summarized in Fig. 2. After having analyzed the monitoring data, the advisor generates a set of suggestions, identifies the most suitable ones for the patient at hand, and applies them to the current insulin plan in order to tackle the metabolic alterations.

The medical knowledge needed to select therapeutic actions is represented through production rules, organized in a taxonomy of classes/subclasses. The main classes are described below.

* Suggestion rules: each rule in this set has a premise which is satisfied when a certain metabolic problem is detected. A more detailed description of the rule class is given in Fig. 3. Rules are divided into subclasses on the basis of the advice they generate: a specific problem might be solved by adjusting the insulin doses, or by revising the diet, or the physical exercise plan. Therefore, every time more than one rule fires, so obtaining a set of alternative solutions to be further evaluated.

Patients and physicians are asked to fill in a form concerning their preferences about the types of actions to be applied to the therapeutic protocol. Five are the possible actions
Fig. 2. Steps of the reasoning process towards protocol revision.

to be carried out: nph or regular insulin dosage adjustments, and meal, snack or physical exercise corrections. They have to be ordered from the most to the less suitable for the patient at hand. Then they are reported on a scale from 0 to 1 [28] and finally a score is calculated for each admissible solution, on the basis of the preferences and of a forecasting of its effectiveness.

When referring to insulin doses, effectiveness is related to insulin activity. The score for an insulin suggestion, concerning an insulin dose given at time 0 and calculated with respect of its effect at time $t$ is hence:

$$ S = IA(t) \times P $$

where $IA(t)$ is the residual insulin activity at time $t$ obtained as in Fig. 4, and $P$ is the preference assigned by the physician (or by the patient) to that particular action. The $IA$ is calculated using the model proposed by Hovorka [29], and depends only on the specific insulin type chosen for the patient at hand.

Therefore, for example, a regular insulin adjustment at lunch would be suitable to solve a problem in the afternoon, while an NPH adjustment in the evening would be applicable to reach normoglycemia in the morning or during the night.

In a similar way we calculate the effectiveness of a given food intake, the score of a meal suggestion will then be high if the problem to solve is present just after the meal time slice. The food activity is calculated as in [30].

When a mild hyperglycemia and some episodes of severe hypoglycemia occur in the same time period, the system, in accordance with the majority of physicians, considers hypoglycemia as a higher risk condition, and generates advice to compensate it.

At the end of the suggestion generation step, the advice set is shown, together with the metabolic problem that originated it.

The following text provides an example of a suggestion rule: it faces a hypoglycemia problem by suggesting to decrease NPH insulin in all the preceding time slices.

IF $X$ IS A PROBLEM
AND THE BGL QUALITATIVE LEVEL OF $X$ IS LOW
AND THE MINIMUM PROBABILITY OF $X > = 0.1$
AND THE TIME SLICE OF $X$ IS $Y$
AND THE NPH INSULIN ACTIVITY IN THE $Y$ TIME SLICE IS $IA$
AND THE NPH PREFERENCE IS $P$
THEN DECREASE NPH DOSE IN $Y$
AND ASSIGN A SCORE OF $IA \times P$ TO THIS SUGGESTION
Temporal rules: not all the suggestions generated in the previous step may be applicable to the patient at hand; indications have to fit the patient’s life style and the physician’s opinions about the most suitable therapy modifications.

As an example, the following rule deletes all the suggestions concerning NPH insulin, to be applied in a time slice in which no NPH insulin can be injected.

IF X IS A NPH SUGGESTION AND THE TIME SLICE OF X IS
NIGHTTIME OR MIDMORNING OR MIDAFTERNOON THEN DELETE X

* Combination rules: even after the deletion of suggestions that resulted to be not admissible for the patient at hand, it is necessary to filter the remaining ones in order to carry out just one action in a single time slice. In fact, more than one correction on the therapy scheme could result in a too strong intervention, and might generate therefore new metabolic alterations.

At the end of this step, the remaining advice is presented to the physician, in order to let her understand what kind of adjustments will finally be applied to the current therapy scheme.

The following rule executes the filtering task:

**IF X AND Y ARE SUGGESTION AND X IS NOT Y AND THE TIME SLICE OF X IS THE TIME SLICE OF Y THEN SELECT THE SUGGESTION WITH THE HIGHER SCORE**

* Insulin plan rules: all the remaining suggestions related to insulin adjustments are applied to the current insulin plan. If the insulin requirement has to be kept constant, when a correction in the insulin dose is performed in a time slice (corrections are always a 10% increase or decrease), another correction of the opposite sign is made in some other slices, so that the daily insulin intake is kept unchanged. Moreover, all the insulin plans stored in the data base are analyzed, and all the ones suitable for the patient at hand are listed. For each of them, the ‘distance’ from the current plan is calculated, by applying the Euclidean distance formula (2) on the insulin doses in the various time slices. For each current-new plan pair we calculate...
\[
\left( \sum_{i=1}^{n} \left( \text{reg}_{i}^{p} - \text{reg}_{i}^{np} \right)^{2} + \left( \text{nphi}_{i}^{p} - \text{nphi}_{i}^{np} \right)^{2} \right)^{1/2}
\]  

over \( n = 5 \) time slices, where \( \text{reg}_{i}^{p} \), \( \text{reg}_{i}^{np} \) denote the dose of regular insulin in the \( i \)-th time slice given in the current and in the new plan, respectively, the same notation holds for NPH insulin. Finally, the selected plans are ordered on the basis of distance and may be easily adapted when premixed insulin is used.

The final choice is left to the physician, who can select one of the suggested plans or edit a new plan: she could get further information from the physical examination of the patient, and therefore conclude that a correction based only on the analysis of the BGL, glycosuria and ketonuria modal day would not lead to a definitive solution.

Moreover, advice regarding meals and physical activity can be used by the patient, under the physician’s supervision, to make adjustments to either the diet or the exercise plan.

The following rule is an example of how to perform NPH insulin adjustments on the plan doses.

**IF X IS A NPH SUGGESTION AND THE TIME SLICE OF X IS Y AND INSULIN PLAN OF THE CURRENT PROTOCOL IS W THEN-adjust W BY APPLYING X IN THE TIME SLICE Y**

4. Implementation

The system is implemented as a distributed environment, composed of a set of MU services and an integrated PU service. The basic structure of the system is shown in Fig. 5.

The PU and MU services cooperate using a common communication protocol and a shared domain ontology describing the structure of the information circulating within the system.

The heart of the distributed architecture is LISPWEB [31], a World Wide Web (WWW) server written in Common Lisp, able to guarantee the automatic generation of HTML pages and the communication among the system components through an extended version of the HTTP protocol, called STSP. The HTTP protocol, that is the protocol on which the WWW is based, is oriented toward the exchange of request-response messages typical of client-server architectures. The STSP protocol, on the other hand, makes it possible to carry out more complex forms of negotiation and dialogue. LISPWEB converts requests made by the patient or by the physician into calls to the different servers of the system, and uses the results to write HTML pages, containing dynamically generated information, shown in different forms, such as multicolon table or plots. The choice of JAVA language has enabled the implementation of animation techniques, useful to visualize all the monitoring data in a single plot, and to immediately identify all the relevant

Fig. 5. Functional view of the system modules.
alterations of a given patient. The use of an extensible and dynamical server such as LISPWEB allows the development of kinds of interaction that can be very complex, but that in the same time are completely transparent to the user, who just has to learn how to use a common web-browser, a kind of program today widely diffuse and quite inexpensive.

5. The system at work

An overview of our system’s capability, and in particular of the therapy advisor, can be obtained considering a real clinical case: our sample patient is a boy of the age of 19, whose diabetes onset took place in 1991. We will focus our attention on a period of 2 months, the typical time interval between two visits. In the month of March 1997, the patient was assigned a three injections plan, in which the daily insulin intake was subdivided into the following percentages:

- 48% of NPH + 8% of regular at breakfast.
- 100% units of 50/50 premixed insulin (i.e. 5% units of NPH + 5% units of regular at lunch).
- 34% units of NPH at dinner.

for a total daily insulin requirement of 0.7 U/kg.

Automatic revision of the therapy was performed on the basis of the data collected in the period March–May 1997.

5.1. Data collection

During the visit, on the beginning of the sample period (12 March), the physician saved in the data-base all the information concerning weight (78.6 kg), HbA1c (8.3%), and results of a physical examination. On the basis of these data the already described insulin plan was chosen, together with a diet of 2805 kcal/day. From that moment on, for the following two months, the boy collected his BGL, glycosuria and ketonuria data in the PU data-base, and contacted the MU only to communicate alarms or messages, when he had problems of bad glycemic control (for example, hypoglycemia after physical exercise: he was suggested to have a snack in the afternoon on the activity days).

5.2. Data analysis

On 21 May, the data received from the PU were analyzed through the data abstraction server, in order to extract the possible problems and therefore to revise therapy. The MD computation identified episodes of both mild and severe hypoglycemia at dinner (see Fig. 6), and of severe hypoglycemia at breakfast and at bedtime; as can be easily seen for the ‘BGL normal’ abstraction (the one in the middle), the maximum and the minimum probability associated to the qualitative value differed for a quantity, visible as a light grey bar on the top of the dark grey column: such quantity represents the ignorance that affects the data, depending on the fact the patient did not always record his BGL values. Anyway the minimum probability of hypoglycemia was always over 10%, a level already considered at risk by the physicians. Instead, hyperglycemia did not reach the probability of 39%, and ignorance was above 15%, it did not represent a dangerous condition, again in accordance with the physicians’ general opinion.

5.3. Automatic protocol revision

Before prescribing a new therapy scheme to the patient, in order to tackle his metabolic control problems, the physician asked the therapy advisor to provide some suggestions for choosing the protocol for the
following period. Before the reasoning process was started, she had to fill in a form concerning her preferences about the possible corrective actions to be applied, and whether to modify the daily insulin requirement: the reasoner is meant to be used by the physician in an interactive way.

The reasoning process executed the following phases:

- Advice generation: each detected problem could be solved by a series of actions (see Fig. 7), in particular, bedtime severe hypoglycemia might be avoided by an increase in food intake at dinner, or otherwise by a reduced dose of NPH insulin at lunch, at dinner, or at breakfast. The low score of the breakfast suggestion is due to the reduction in insulin activity during the all day. The advisor also suggests to reduce the regular insulin dose at dinner, but it was not applicable to the plan at hand, as regular insulin injections were scheduled only at breakfast and at lunch.

Hypoglycemia at dinner might be fought by decreasing NPH insulin at breakfast or at lunch, or by decreasing regular insulin at lunch (if a regular dose at midafternoon was scheduled, it should be reduced).
Fig. 7. All the suggestions generated by the system.

Finally breakfast hypoglycemia could be fought by reducing the regular insulin dose at dinner (or at bedtime, if there was one).

* Advice selection: on the basis of the physician’s preferences, of the patient’s lifestyle and of insulin activity during the day, a smaller set of suggestions was selected. It was proposed to reduce the percentage of NPH insulin at breakfast and at lunch, while the hypoglycemia problem at bedtime would be solved by increasing the food intake at dinner, as this adjustment was more effective than an insulin reduction in the same time slice: in fact the patient only assumed NPH insulin at dinner, and the NPH activity at bedtime was quite small, therefore the score assigned to the NPH reduction suggestion was lower than the one of the meal increase. The insulin plan did not contain a regular dose at midafternoon or an NPH dose at bedtime: the suggestions concerning these time slices could not be applied (see Fig. 8).

* Plan revision: the reasoner first calculated a possible insulin plan that was a manipulation of the current one, in which the
breakfast NPH insulin percentage was reduced by 10%. Then it found all the library plans that followed the selected advice, and were therefore suitable to solve the current problems. Finally it ordered them by minimizing the difference in the insulin doses in the various time slices. The physician chose the most strongly recommended plan (see Fig. 9), and just made a couple of adjustments before assigning it to the boy: she did not only decrease the NPH lunch insulin dose but also the regular one, in order to let the patient still use a 50/50 premixed insulin; moreover she preferred to decrease the NPH insulin dose, instead of increasing the food intake at dinner.

6. Conclusions

In this paper, we have described the protocol-based reasoning features of a system for the management of IDDM patients. The system we have implemented provides patients with an instrument that gives them support for data collection and teleconsultation. On the other hand, it supplies to physicians a set of tools able to visualize and analyze the patients’ monitoring data, in order to detect eventual metabolic problems, if any alterations have been identified, the protocol-based reasoner, realized through the ESPM, adjusts the therapy to tackle them, in accordance with the patients’ needs.

A central role has been reserved to the care-provider, and her opportunities of interaction with the reasoner will increase in the extensions we are working on. At the most general level, the physician will be able to decide whether to use the already implemented protocol-based reasoning tool, or a case-based one, according to which the most strongly recommended protocols would be the ones
that solved similar problems when applied to a large number of patients. Moreover, the physician will be able to choose the metrics to order protocols, or what kind of statistical analysis (in addition to the modal day computation) have to be carried out on the patient’s data, thus supplying a different input to the reasoner and activating different sets of rules. The system is being developed within a 3-year project, started in June 1996. The verification phase of the project will start by the end of the year, and it will be carried out by testing the services on a group of ten patients chosen in the pediatric department of the San Matteo hospital in Pavia.

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