

Application Report: Preliminary Evaluation of the T-IDDM Project in Pavia

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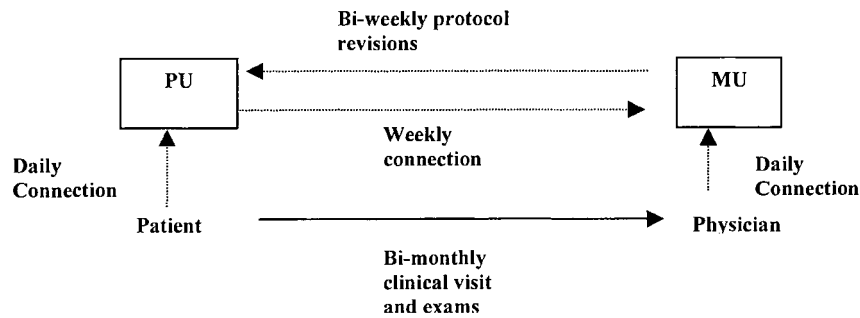
We present the preliminary results of the verification phase of the EU funded T-IDDM [1,2] (Telematic Management of Insulin Dependent Diabetes Mellitus) project, collected at the Pediatric Department of Policlinico S. Matteo Hospital in Pavia.

The T-IDDM architecture is composed by two main elements: a Patient Unit (PU), devoted to collecting data and to providing suggestions to patients, and a Medical Unit (MU), that supports physicians in the overall patient management process. The two units are connected through a telecommunication system, that allows the patients to send their home monitoring data, and the physicians to revise and send back the therapeutic protocol in the light of the collected information; moreover patients and physicians may rely on an e-mailing system to maintain a continuous interaction and to better manage the monitoring task. The MU provides physicians with a collection of Web-based services, such as data management and retrieval, decision support, and communication. Each PU is a PC-based software, running at the patient's house, and interfaced with commercial instrumentation for Blood glucose Level readings.

In the implementation of the T-IDDM architecture we developed in Pavia, the PU is connected to the hospital through standard Public Switched Telephone Lines, while the distributed services of the MU are accessible over the Local Area Network of the Policlinico S. Matteo hospital. In particular, all patients' data are stored in an OracleTM data-base, residing at the hospital EDP, while the intelligent data analysis and the decision support tools run on a workstation at the Scientific Direction. The communication among the elements of this distributed system, as well as with the PU, relies on **lispweb** [1], an HTML/HTTP server written in Common Lisp. All services are routinely accessed from the Pediatric Clinic Department.

The T-IDDM verification phase started at the Pavia site in the period April-June 1998, and currently involves 4 pediatric patients, 2 diabetologists, 2 physicians under training programs on pediatrics, 1 nurse and 1 dietician.

The project has been evaluated by the ethical committee of the Policlinico S. Matteo Hospital, and a detailed consensus has been signed by the involved patients.



The protocol applied during this first evaluation phase is described in the figure above. Moreover, other information was collected in these months, such as the frequency of the data flow, the frequency of ambulatory visits, and the impact on the physicians workflow is being carefully analyzed. Moreover, the usability of the interfaces, and the usefulness of the collection of decision support tools is under consideration.

The preliminary results obtained up to March 1999 at the Pavia center are shown in the Table below:

Parameters of the period June-March 1999	
Follow up days	270
Distance between consecutive data communications	4-7 days
Number of messages sent by physicians	23-39
Number of messages sent by patients	28-44
Number of BGL per patient per day	1.44-3
Average HbA1c modification	-0.66 (sd 0.7)
Number of protocol changes	4-7
Schedule	
Physician consultation	Daily
Patient consultation	Daily

Although the small number of patients does not allow to obtain statistically significant results, there are several interesting issues that arise from the collected data. First, the high frequency of logging on the system, and the high number of messages exchanged between patients and physicians demonstrates that both patients and physicians have found helpful to rely on the system's functionality, and that the system is quite easy to use, having a sufficiently user-friendly interface; a quantitative evaluation of these indicators will be provided through the examination of some usability questionnaires that have been distributed to patients and physicians. The weekly schedule has been nearly maintained, as well as the required BGL measurements per day.

Moreover, the average number of protocol changes has been nearly doubled with respect to clinical practice; when working without the system support, the physician just evaluates the patient's condition on the visit day, while T-IDDM permits him to verify the metabolic state more frequently. In such a way, if a problem arises, the patient does not have to wait, as the physician is immediately able to make a therapy revision to cope with it.

We believe that such an increased frequency in therapy adjustments has led to a reduction of the mean HbA1c level in the patients under monitoring: helped by the system, physicians have

been able to better and sooner understand the patients' peculiar needs, and to define insulin treatments properly tailored on the specific situation under examination. Finally, it is of interest to consider the data coming from one patient in a greater detail. The following table shows the Blood Glucose Level descriptive statistics calculated over two different periods, one at the beginning of the verification, and the other at the end. It is easy to see how the use of the system improves not only mean and median, but also the standard deviation, that is known to be an important risk factor in patient's treatment.

	Breakfast		Lunch		Dinner	
	1/4/1998 30/6/1998	1/12/1998 28/2/1999	1/4/1998 30/6/1998	1/12/1998 28/2/1999	1/4/1998 30/6/1998	1/12/1998 28/2/1999
Mean	186	184	165	156	167	159
Median	200	184	152	143	162	141
SD	55	60	65	59	69	70
Min	72	62	63	56	61	52
Max	345	304	355	287	322	389

References

- [1] Riva A, Bellazzi R, Stefanelli M. A Web-Based System for the Intelligent Management of Diabetic Patients. MD Computing. 1997; 14:360--364.
- [2] Bellazzi R, Cobelli C, Gomez E. and Stefanelli M. The T-IDDM project: Telematic management of Insulin Dependent Diabetes Mellitus, Health Telematics '95, (M. Bracale, F. Denoth eds.); 1995: 271—276