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ARTICLE *in* COMPUTER METHODS AND PROGRAMS IN BIOMEDICINE · SEPTEMBER 2002

Impact Factor: 1.9 · DOI: 10.1016/S0169-2607(02)00039-1 · Source: PubMed

ELSEVIER

Computer Methods and Programs in Biomedicine 69 (2002) 163–177

Computer Methods and Programs in Biomedicine

www.elsevier.com/locate/cmpb

Telemedicine as a tool for intensive management of diabetes: the DIABTel experience

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Received 14 May 2001; received in revised form 17 July 2001; accepted 31 August 2001

Abstract

This paper presents the current features of the DIABTel telemedicine system and the evaluation outcomes of its use in clinical routine. This telemedicine system is designed to complement the daily care and intensive management of diabetic patients through telemonitoring and telecare services. The system comprises a patient unit (PU) used by patients in their day-to-day activities and a Medical Workstation used by physicians and nurses at hospitals. Both applications offer tools to collect, manage, view and interpret data and to exchange data and messages. The system was evaluated for usability, telemedical protocols, metabolic control and quality of life. This evaluation consisted in a 6-month cross-over pilot study with ten Type I diabetic patients. The results of the evaluation allowed assessment of the telemedicine protocols in terms of the number of communications/patient (21.6 ± 7.7); days between communications (5.4 ± 2.66); messages sent by physicians (118 text messages); and data and messages transmitted by patients (3524 blood glucose readings, 1649 day-to-day insulin adjustments, 24 exercise reports, ten diet modifications and 63 text messages). Physicians performed more therapeutic changes during the DIABTel period than in the control period. There was a trend towards HbA1c improvement during DIABTel use with no incidence in the number of hypoglycaemias. This pilot study demonstrates the feasibility of the DIABTel system in clinical routine use and its potential benefits for diabetes care: improving the availability of information necessary for therapy adjustments; offering new physician–patient communication tools; increasing patient empowerment and education; and showing a positive trend towards improving the metabolic control of patients. Further studies are needed to validate these findings and to promote telemedicine as an opportunity to better diabetes care.

Keywords: Telemedicine; Diabetes care; Clinical evaluation; Patient supervised autonomy

1. Introduction

In Western societies, diabetes and its complications are still causing a tremendous amount of suffering in over 5% of the population. It contin-

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0169-2607/02/$ - see front matter
PII: S0169-2607(02)00039-1

ues to be a major health problem and amounts to as much as 8% of national spending in health care [1]. Diabetes is a chronic disease characterised by a sustained elevated blood glucose level, caused by a reduction in the action of insulin secretion where related metabolic disturbances generate severe, acute and long-term complications that are responsible for premature death and disability [2].

Nowadays, a well-treated Type I diabetic patient can expect to have an almost normal life span as the benefits of intensive management have been well established and include reduced long-term complications [3]. Nevertheless, the achievement of the therapeutic goals and current guidelines [4] implies a significant increase in the amount of patient data to be monitored, the need of a tight control of patients in their self-monitoring blood glucose levels and day-to-day insulin adjustment, requiring in many cases a better patient empowerment and education, increasing physicians and nurses workload and raising immediate health care costs. On the other hand, the inability of a large proportion of the population in the more affluent western societies to cope with the excess caloric supply together with a lack of physical exercise results in a greater prevalence of Type II diabetes. This fact can be seen in figures: at least 100 million people today suffer from Type II diabetes and by 2010, this will rise to 215 million [5]

During the last two decades, diabetes has been a major clinical focus for advances in information technology, telemedicine developments and intelligent systems [6]. Due to its multifactorial and systemic character, diabetes mellitus has been considered a paradigm of chronic disorders which has led to the application of information technologies in diabetes care [7]. Applications have been classified taking into account several approaches such as the system end-user, namely the patient or the physician [8] to provide them with tools to support their daily tasks in diabetes care, or under more general technological headings such as clinical databases, therapeutic algorithms, decision support systems [9], modelling and educational tools [10]. Telemedicine provides an integrated approach to those tools, which enhances co-operation between users and information sharing and knowledge (see Fig. 1).

Nowadays telemedicine is radically changing healthcare models particularly in the way healthcare is currently delivered [11]. It is transforming the relationships between healthcare administrations and companies, professionals and patients. Furthermore, Internet is changing the way patients gather information about diseases and

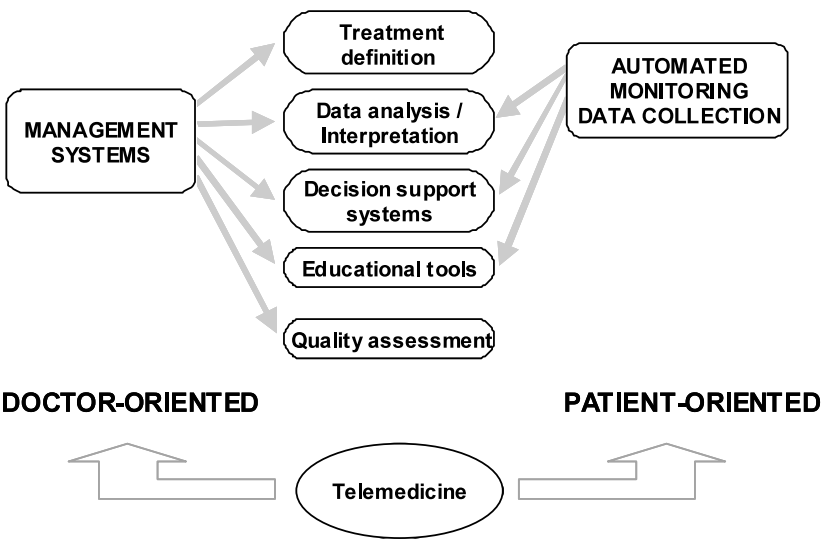

Fig. 1. Classification of end-user tools for intensive management of diabetes.

drugs and is allowing them to communicate directly with their physicians. The need for more and better health care information is confirmed by the fact that health-related sites are among the most frequently accessed information resources on the Web [12,13].

Earlier experiences of telemedicine in diabetes management aimed to improve communication and co-operation between patients and doctors [14] and in many cases only comprised the transmission of computerised blood glucose profiles by telephone modem-based home glucose monitoring equipment [15]. In some of these experiences, and as an extension of remote patient data monitoring, patients received advice over the telephone on insulin adjustments and food intake after transferring results to the clinical centre [16].

Over the last years the search for increasing the possibilities offered by telemedicine in diabetes care has led to a growing number of experiences covering several technological approaches and scenarios of care delivery [8]. For home care several approaches for therapeutic advice delivery to patients at home have been reported [17–19]. Recently, telemedicine is being applied in wide scale healthcare experiences as a main tool for the delivery of home care and diabetes education to patients [20].

This paper presents the current development of a telemedicine system, DIABTel, which complements the daily care of diabetic patients, and the pilot study conducted to evaluate the system usability and users acceptance, to characterise the telemedical protocols and to analyse the impact of the system use on the patients metabolic control and quality of life.

2. Telemedicine procedures for diabetes care through DIABTel

In conventional diabetes care, patients' status and glycaemic control is normally assessed by the physician/nurse during the visit to the clinic and is based on the patient's reported monitoring data and other clinical indicators such as glycosylated haemoglobin readings. The communication between the hospital diabetologists and patients is in many cases restricted to the maximum number of visits to the clinic which are normally scheduled every 3–6 months. Furthermore, the doctor's workload restricts the visit time assigned to each patient.

One of the main goals of the DIABTel system is to enhance the possibilities of traditional clinical procedures providing both doctors and patients with an integrated service to manage and improve several aspects of daily diabetes care. The system can be a care tool for all diabetic patient populations (Type I, Type II, gestational diabetes, other types), including those with severe long-term chronic complications and disabilities.

The DIABTel architecture [8] is based on two main components: the Medical Workstation (MW), a PC-based application used by physicians and nurses at the hospital, and the patient units (PU), implemented on a palmtop computer and used by patients during their actual daily living.

At the hospital, the telemedicine service runs 24-h a day receiving and processing the patients' monitoring data, messages and requests for doctors' advice. Any feedback to the patient is transmitted whenever the patient decides to connect the PU to any public switched telephone network. The PU can be set to transmit data through a direct phone call to the DIABTel server or through a TCP/IP (point-to-point protocol—PPP) connection through any Internet Service Provider.

2.1. Services for diabetes care

The DIABTel system supports physicians with telemonitoring and telecare tasks between face-to-face hospital visits. The system makes available all the information needed for patient management and for decision making in therapy planning. These telemedicine services are the following:

2.1.1. Telemonitoring service

Telemonitoring affords physicians the remote supervision and control of patients' data in the period between two hospital visits. Telemonitoring comprises the recording, transmission and visualisation of the main variables considered in diabetes care: blood glucose levels, diet, insulin

dosage, physical activity and other related aspects (i.e. ketonuria, drug intake and fever).

2.1.2. Telecare service

The telecare service permits the physician to remotely care for the patient and allows patients to ask for advice on daily care management situations. This service comprises two other complementary features: teleconsultation and supervised care.

- Teleconsultation: This service supports message exchange between patients and doctors. It is an asynchronous facility initiated by the patient sending a message to the doctor asking for advice or for explanation of some data. The doctor answers the request within the following 24 h.
- Supervised care: This service provides the patient with a 'supervised autonomy' on diabetes self-management. After data reception, the doctor studies all the available information and decides whether to advise the patient on treatment adjustment, confirm the short-term therapeutic decisions taken by the patient on his own, or whether to ask him to attend the hospital.

2.2. Telemedicine protocols: DIABTel at work

The telemedicine services implemented in the DIABTel system modify the conventional diabetes care process by providing a new means for patient–doctor interaction in between scheduled hospital visits. This system also keeps physicians more informed of deviations in the metabolic control that require therapeutic interventions or educational recommendations.

An IT system for chronic care has to cater for the main requirements for physicians' decision making. It must provide enough information to enable assessment of the patient's condition and must present the relevant patient clinical data to define a therapeutic change. In the case of diabetes mellitus the responsibility of data collection is shared between patients, who record data during daily life (self-monitoring data) and the healthcare personnel, who capture data during hospital visits (hospital patient record). The DIABTel telemonitoring service makes available the patient's self-monitoring data whenever a doctor wants or needs to assess the patient's state. Therefore, telemedicine changes the conventional clinical protocol and presents the question of when the patient status assessment must be done using a telemedicine protocol.

In conventional diabetes care, the patient visit activates the metabolic state assessment in the current care process. In the DIABTel telemedicine protocol (see Fig. 2) the patient state assessment can be additionally activated by three reasons: (1) the reception at the MW of patient monitoring data showing undesired data patterns; (2) the teleconsultation from patients to doctors; and (3) whenever the doctor considers necessary (i.e. 1 week after a therapy adjustment).

The telemedicine protocol starts by registering the patient to be managed by DIABTel and by opening a new electronic patient record (EPR) at the hospital, including the prescribed insulin therapy and diet plan. The patient is provided with a PU to use during his/her normal life to collect and consult monitoring data. The PU is set with the patient's own therapy and blood glucose normal ranges and includes an electronic logbook (data entry, data visualisation and statistics); an electronic mail facility; and consultation of the prescribed insulin therapy, diet plan and meal information. The patient records daily therapeutic decisions (i.e. day-to-day insulin adjustments) made by himself to cope with abnormal metabolic values and to adapt the set therapy to his meals and physical exercise. The transfer of information between the PU and the MW can be activated by the patient at any time by plugging the PU to a public telephone network. After receiving data or a message from a patient, the patient state assessment is activated. The MW notifies doctors when messages and/or data with associated alarms are received and offers them tools for data analysis (patient logbook visualisation, graphics and statistics), therapy definition and messaging. The result of doctors' analysis can be a text message containing a recommendation and/or therapy adjustment that is sent back to the PU the next time the patient activates the communication.

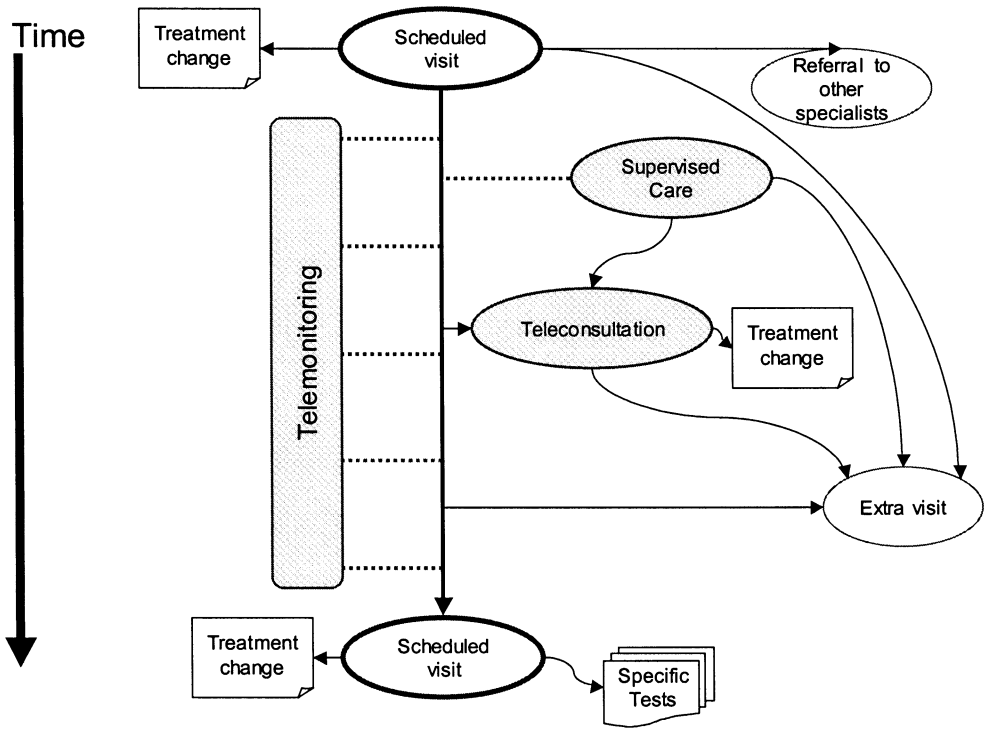

Fig. 2. DIABTel diabetes care telemedicine protocol.

During the face-to-face visit, physical examination and tests are performed to detect any new complications and to assess the development of the patient's condition. The EPR is then updated with this new information.

The following sections describe in detail the diabetes care process supported by DIABTel and the information flows between users.

2.2.1. EPR, visit management and therapy definition

The MW allows a complete outpatient EPR to be kept. This stores general information about patients, including any existing complications or illnesses associated to diabetes. This EPR is based on the data set used at the Sant Pau Hospital in Barcelona to fulfil the outpatient Diabetes Service requirements.

DIABTel also implements a 'visit management' module which is updated during the patients visits to the hospital according to the outcome of any examinations and tests performed. This helps to detect any new complications and to assess the development of the patient's condition (see Fig. 3). Clicking on any clinical value on the screen with the right-hand mouse button shows the development of the selected variable over a number of hospital visits.

The treatment management scenario completes the MW functionality related with clinical information. It allows the creation of a new treatment (insulin therapy, dietary plan and target glycaemia ranges) and the consultation of previous therapeutic plans. When a new treatment is defined, it is automatically labelled as 'awaiting transfer to the PU'. It remains in this state until it is transferred to the PU the next time the patient connects his/her PU for data exchange with the MW. As PU-MW communications are asynchronous, the MW clearly shows the doctor whether or not the therapy has been delivered to the PU.

2.2.2. Patient self-management

Patients are provided with a PU configured with their own therapy and blood glucose normal ranges. The tools afforded by the PU are:

- An electronic patient logbook, which includes
  - Data entry. Patients can register self-monitoring blood glucose both manually or through automatic download from the glucose meter; comments to BG values; day-to-day insulin adjustments; modification of the diet plan; physical exercise and other events relevant to the interpretation of blood glucose levels.
  - Graphical data visualisation and statistics. Patients can perform different plots of blood glucose values within selected time spans (i.e. raw data and summaries associated to specific moments throughout the day). Additionally the PU shows the statistical performance over the plots.
- Electronic mail. Patients can send text messages to the care team, read the new messages received after a communication and organise the past messages.
- Consultation of the prescribed insulin therapy, diet plan and meal information. When a new therapy is defined at the MW, it is shown in this PU user interface scenario.

The transfer of information between the PU and the MW is activated by the patient plugging the PU to a public telephone network. Afterwards the patient receives feedback on the information transferred from the PU to the MW and vice versa. In order to receive a message or answer from the health personnel an additional connection is needed to retrieve it.

2.2.3. Co-operative electronic mail

Patients can send messages to doctors including text and/or data collected at the PU. The func-

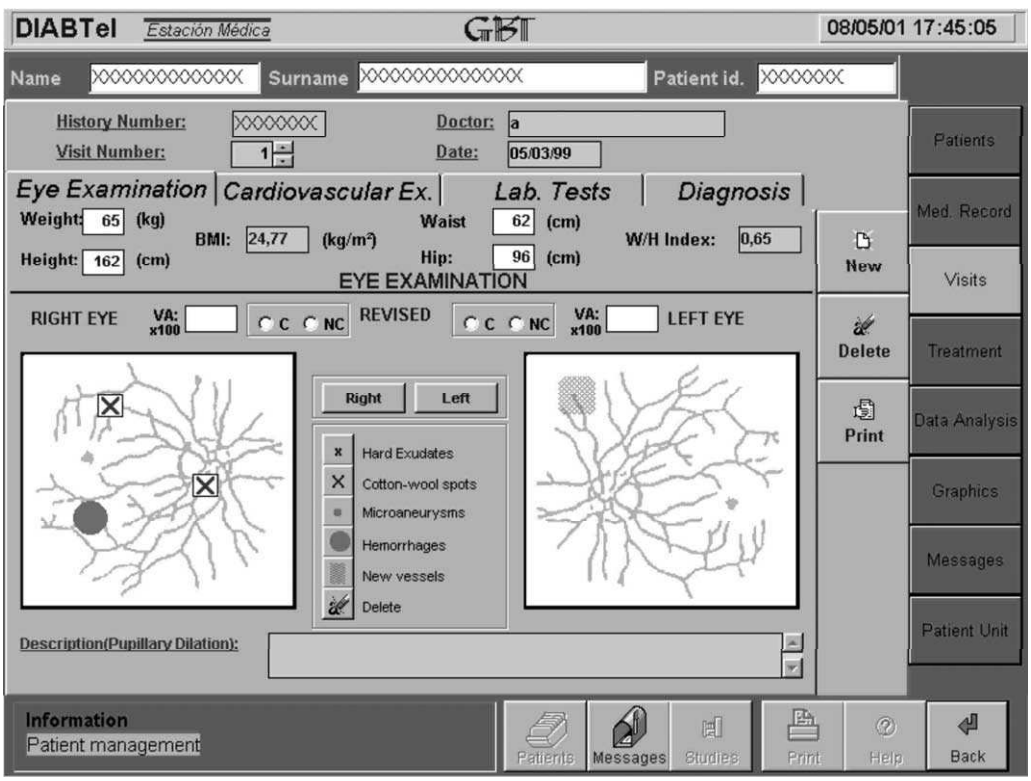

Fig. 3. Medical Workstation screen showing the visit management scenario with an example of patient retinopathy assessment.

Fig. 4. Medical Workstation message management screen.

tionality of the message management module is similar to an enhanced e-mail system where text messages can have attached non-textual information. This co-operative mail integrates automatically, within the text message, relevant information from the patient's electronic record, monitoring data, alarm messages, data summaries and acknowledgements of therapeutic changes reception. Whenever a message is received, the MW processes the content of the information and looks for abnormal data to activate alarms that will be presented to the physicians. Patient data is also updated in the database and is available from any other modules. Fig. 4 shows the user interface for consulting any text message and the summary of the associated data.

When doctors start a working session at the DIABTel MW, they can check the list of new messages to search for alarms which are highlighted in red. By simply pressing a button, doctors are linked to the graphical analysis module to perform a deeper analysis of the data received. Doctors can also send text messages to the patients containing their comments or advice. In addition, any modification in the patient therapy or in the PU configuration (i.e. the hospital phone number) also generates a message to be sent to the patient. All those messages are loaded in the MW mailbox waiting for the recipient to connect his PU. Physicians can check whether a text message or therapy adjustment has been delivered to the patient by consulting the output mailbox and where they may also modify or delete any pending messages.

2.2.4. Data analysis and decision making

A telemedicine system increases the amount of data and information used by doctors and modifies the therapeutic decision making procedures. Therefore, it must provide a set of data analysis tools for numeric and graphical visualisation data summaries, comparison of data monitoring for time periods associated with therapy changes and automatic report generation. All these features are supported by DIABTel MW, which together with the co-operative electronic mail, allows doctors to supervise patient care.

- Electronic patient logbook

The electronic patient logbook shows monitoring data collected by patients such as blood glucose readings associated to their related events (diet modifications, insulin administrations, schedule modifications, illness, etc.) (see Fig. 5). Blood glucose values are colour coded to highlight whether they are within the target ranges, near to the limits or whether they classify as hypoglycaemia or hyperglycaemia according to the ranges selected by the physician for each individual patient.

- Graphical visualisation

A range of data analysis possibilities are available for comparison of time spans with different therapies and for visualising data summaries to simplify and minimise time for decision making on therapy adjustments.

- Report generation

Different reports may be printed out and added to the conventional patient record (i.e. physical examination results obtained in a visit, graphical representation of a period) or delivered to the patient (i.e. definition of the insulin therapy and

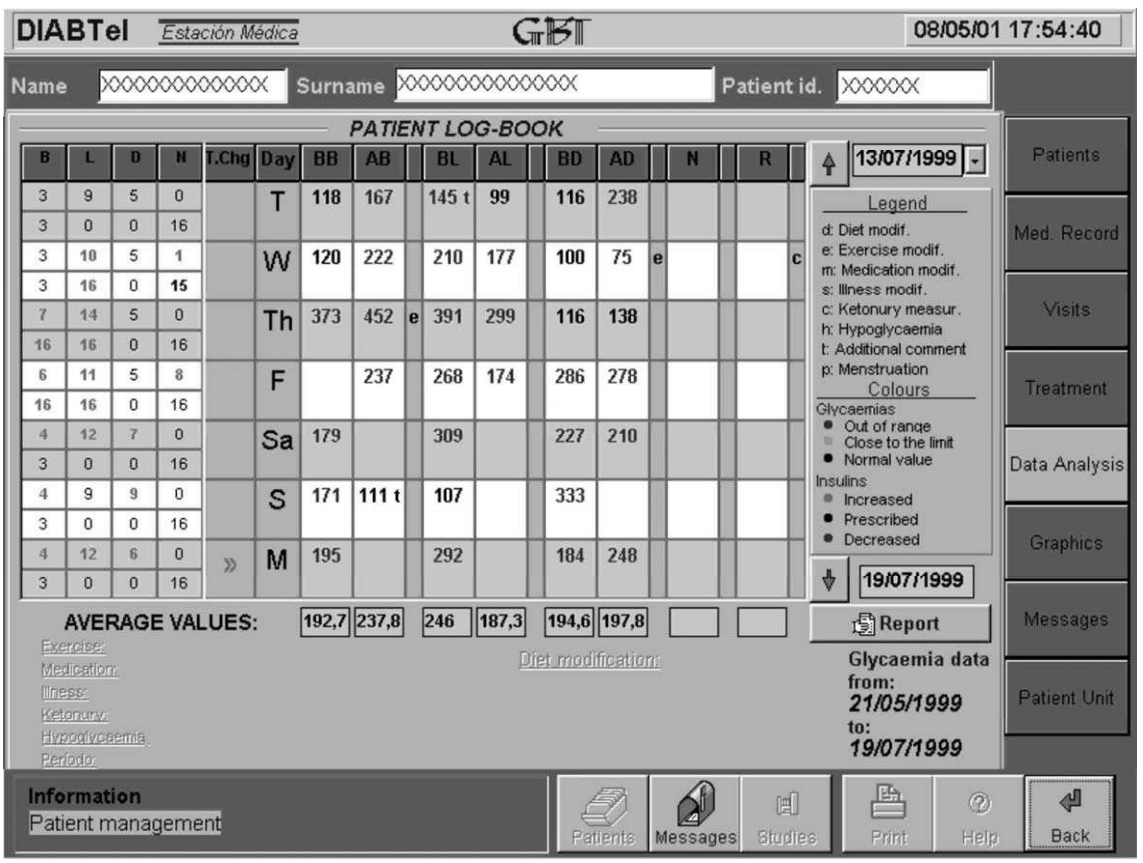

Fig. 5. Medical Workstation electronic patient log-book.

diet, patient logbook). A preview function displays the report to check its content or to add further comments before printing.

2.2.5. Web-based access to DIABTel MW

Physicians and nurses can remotely access the information contained in the DIABTel clinical database using a Web application. The 'look and feel' of the Web application is similar to the DIABTel MW user interface which increases the system's usability. The functions available in this Web service includes messaging with patients, visualisation of self-monitoring data, consultation of insulin therapy and diet plan and access to information registered during the hospital visits.

3. Pilot study

The DIABTel system has been evaluated in a clinical study carried out over a period of 14 months at the Diabetes Centre of the Endocrinology Department in Sant Pau Hospital (Barcelona, Spain). The pilot study goals were to demonstrate the feasibility of DIABTel in routine clinical use and to analyse its impact on delivering a better care for diabetic patients. For these purposes, a thorough evaluation methodology was designed to assess the telemedicine service.

3.1. Description of the trial

The trial consisted in a 6-month cross-over study involving ten Type I diabetic patients with a DM duration of 13.8 ± 6.5 years. Patients were randomly selected to participate in either one of the trial's two parallel 6-month phases, the DIABTel study and the control; and were switched to the other part of the trial half way through the trial. The patient selection process was carried out in line with the following criteria: patients had to present an inadequate metabolic control and DM duration of over 5 years.

During the study patients had to attend three programmed visits at the hospital: one at the beginning of the trial, one at the crossover from one group to the other and one at the end of the study. Additional potential contacts between doctors and patients were occasional visits to the Diabetes Centre in emergency situations or phone calls to the permanently available 'Diabetes Centre telephone link'.

3.1.1. Control period

In this period, patients used a blood glucose meter with memory (One Touch™ Profile from LifeScan) and additionally they registered the monitoring data in their conventional logbook. No intermediate visits were scheduled to the hospital but patients were free to make phone calls to the Diabetes Centre when needed. At the end of the period patients had to visit the hospital and the metabolic control was assessed using blood glucose data downloaded electronically and the HbA1c measurement.

3.1.2. DIABTel period

During the DIABTel period, patients used a PU and the same blood glucose meter as in the control period. Blood glucose readings were directly downloaded into the PU, connecting the meter to its RS232 port. Patients could manually register any kind of monitoring data in the PU electronic logbook: blood glucose readings, insulin changes (dose, type), diet modifications and additional events, such as illness, ketonuria, additional drug therapy, severe hypoglycemias, etc. Patients could also write messages to the care team. Patients were advised to use the PU at any time and at any place (home, work, travel,...), although they were asked to send their self-management data and/or messages to doctors at least once every 2 weeks. Whenever new data was received, doctors had to analyse it and provide feed-back within the next 24 h (working days). New data is highlighted in red on the MW main screen. Doctors' answers included text messages with advice, requests for information, insulin therapy adjustments (doses, site, time injection-meal) or diet plan modifications.

3.2. Evaluation methodology

The methodology designed to evaluate DIABTel covers three different and complementary phases:

(a) Evaluation of the Telemedicine protocols.

The goal of this evaluation phase is to characterise the use of telemedicine in the clinical practice and the suitability of the telemedicine protocols.The following parameters were included in the analysis:

- No. of communications per patient using the PU
- No. of messages per patient to/from the hospital
- No. of therapy modifications between two visits
- No. of alarms received at the DIABTel MW
- No. of telephone contacts

(b) Evaluation of system usability.

The goal of this phase is to analyse the user's behaviour and feelings when using the system. The methodology used in this evaluation phase has already been reported in the author's previous work [21,22]. Evaluation is based on subjective questionnaires designed for patients and doctors in order to evaluate both the medical workstation and the PU. These questionnaires acquire information on several issues such as; the previous experience with similar IT applications or the opinion of users when interacting with the information systems (degree of achievement of the user's tasks, efficiency, easy to use, help, application control, easy to learn, perceived reliability and user acceptance).

(c) Clinical evaluation of the system.

The goal of this phase is to analyse the telemedicine system's impact on the actual quality of the patient's care compared with conventional care. The clinical parameters analysed at the end of each period are HbA1c, mean of blood glucose values, severe hypoglycemic events and changes of therapeutic protocols decided by patients/doctors. To complete the evaluation of the DIABTel telemedicine service we included some subjective items in the patients' questionnaire to obtain information on the quality of doctor–patient communication when using DIABTel and also on the advantages DIABTel offers over conventional procedures [23].

3.3. System installation and integration in clinical routine

The installation of a telemedicine system into the existing clinical routine procedures produces changes in the existing organisational and clinical protocols. A strategic installation plan was designed to minimise difficulties and manage the increase in doctors' workloads during the first stages of implementation of the telemedicine service. This strategic plan included several organisational and technical issues described below.

The installation plan included the compilation of complete user guides for the Medical Workstation and the PU. These guides were delivered to users during the training sessions. All this documentation was carefully thought out to provide for easy comprehension for users unfamiliar with computers and technical terminology.

The technical issues related to the integration of DIABTel in the hospital included:

- implementation into the MW of an EPR, based on the paper record used in the hospital department
- provision of technical support and maintenance, both locally at the hospital and remotely (tele-maintenance) from the developer team
- other safety features such as a backup strategy to guaranty the retrieval of the DIABTel databases.

4. Evaluation results

This section presents the outcomes of the evaluation carried out during the pilot study, including the telemedicine protocol, PU usability and clinical evaluation.

4.1. Telemedicine protocol evaluation

The number of communications performed by patients using the DIABTel PU was 18.8 ± 7.4 per patient. This figure implies that patients were communicating with the MW around once per week (6.75 ± 4.09 days between consecutive communications).

Most of these communications were established to transmit monitoring data. In total, patients transmitted 3524 blood glucose readings, 1649 daily insulin adjustments, 24 exercise reports and ten diet modifications. The total number of text messages sent by all patients was 63 showing a very limited use of the possibility of an 'electronic' communication with doctors.

On the part of the medical team, during the DIABTel study physicians replied to patients with a total of 118 text messages including not only the answers to patients' requests but 37 therapeutic modifications after analysis of the data received. Physicians performed more therapy changes during DIABTel than in the control period: 2.9 ± 2.17 vs. 0.2 ± 0.4 due to their possibility to assess the patient's condition on a frequent basis.

The number of phone calls for therapy consultations to the diabetes centre was similar in both periods: three patients phoned to the DC for therapy advice during the DIABTel period whereas two patients calls were made in the control period. The therapy changes decided by patients were similar in both periods: 1 ± 1.18 DIABTel vs. 0.5 ± 0.67 control.

4.2. PU usability evaluation

Only two patients (out of ten) had previous experience with computer applications for managing self-monitoring data. Three patients were feeding blood glucose data manually, two patients used only the automatic download from the glucose meter and the other five used both methods.

The patients' questionnaire was divided into three sections: general issues (see Table 1), usability aspects (see Table 2) and system utility as a support in the management of diabetes care (see Table 3). The patients' answers are scored from 1 (bad) to 5 (excellent).

The usability scores presented in Tables 1 and 2 were highly influenced by the PU user interface limitations (keyboard size and screen) and by technical problems with the pocket computer hardware reliability (HP200LX Palmtop), i.e. battery drain when communicating data through the modem. Despite these drawbacks, patients found that the system has high utility and considered that it should be of general use in diabetes care (see Table 3).

Table 1
Evaluation of general issues (data are number of patients)

General issues	Bad (1–2)	(3)	Good (4–5)
Data access	2	2	6
Data interpretation	3	1	6
Communication			
Natural	2	2	6
Frequency	1	1	8
Problems	5	1	4
Help on DM control	1	0	9
System response time	4	1	5
Global	18	8	44

Some of the patients' comments related to the main benefits of the DIABTel system such as: improved patient–doctor communication; availability of data analysis and display tools; increased confidence in the daily therapeutic self-management due to the constant supervision; and increased patient empowerment. The summary of drawbacks reported by patients when using the PU were: the limitations of the PU user interface and its slow processor; the need for too many cables to plug in the PU to the telephone line and the BG meter to the PU; the size of BG meter and the pocket computer system reliability.

Table 2
Evaluation of usability (data are number of patients)

Usability	Bad (1–2)	(3)	Good (4–5)
Efficiency			
Data Collection	3	1	6
Data Consultation	3	2	5
Treatment changes	2	2	6
Easy to use, friendliness			
Easy to use	1	3	6
Comfortable	2	2	6
Help (guidance)	3	3	4
Easy to learn	1	2	7
Reliability	2	1	7
Global	17	16	47

Table 3
Evaluation of utility (data are number of patients)

Utility	Poor (1–2)	(3)	Good (4–5)
Glycaemic control improvement	0	3	7
Make easy treatment changes	1	0	9
Make better communication with doctor	3	0	7
Help on DM education	2	1	7
General use in diabetes care	1	1	8
Provide advantages vs. traditional procedures	2	2	6
Global	9	7	44

4.3. Clinical evaluation

The median value of HbA1c was: 8.10 (6.6, 9.1) at the beginning of the control study; and 8.4 (6.9, 9.1) at the beginning of the DIABTel study. The HbA1c was 8.15 (5.9, 9.9) at the end of control study and 7.9 (6.6, 8.9) at the end of DIABTel study. These figures show a trend towards reduction of the HbA1c after the DIABTel study ($P = 0.053$). The number of hypoglycaemias per week was similar in both studies and no significant differences in the quality of life were found. A Wilcoxon-rank test has been used for comparison, and statistical criterion significance was set at $P < 0.05$. Further details about the results of the clinical evaluation can be found in [23].

5. Discussion

Telemedicine alters the conventional diabetes care processes, not only by the use of information technologies (IT) to manage information in an electronic media, but also because the interactions between patients and doctors have a different timing and are of a different nature than in face-to-face visits. Telemedicine services afford the assessment of a patient's state on more frequent basis than in conventional clinical procedures and most of the time this assessment can be done by doctors 'in background' at the hospital until any indicator suggests that clinical action should be taken. These new 'telemedical' procedures are implemented by the DIABTel system to achieve the goal of 'supervised autonomy', which increases patients' independence and ability to make their own decisions without decreasing the necessary continual support and specialist supervision.

The DIABTel system implements asynchronous telemedicine procedures that require doctors to make their decisions from a distance. This does have a significant drawback compared to the traditional face-to-face encounter. Doctor decision-making is based on the information available, without the possibility of getting more information from the patient in real time. In diabetes care, these constraints affect the quality of the information as the blood glucose measurements are not the only aspect to consider; other relevant data is necessary to interpret them. These limitations lead to the need to offer tools for doctors and nurses to manage the EPR efficiently. This record is the core of any telemedicine system as it allows analysis and display of the self-monitoring data in a more easy and summarised way. The DIABTel system provides an integrated approach for both doctors and patients to manage clinical data and to help decision-making. A more sophisticated approach to this problem would imply the use of intelligent decision-support systems [24] to help on issues concerning to the detection of uncontrolled metabolic trends, the need for therapeutic changes or the proposal of treatment adjustments. Several approaches of knowledge-based systems have been developed for telemedicine systems in diabetes care [25]. Intelligent procedures [21] are currently being integrated into DIABTel to provide decision-support for therapy planning and to build automatic intelligent alarms for both patients and doctors.

The need to provide information technology solutions for patient empowerment at any time and in any place or patient situation means that the service should be as ubiquitous as possible. The aim would be to create a smaller size PU. This unit would need to be completely portable, very powerful (speed processor and memory), very simple to use and manage (high usability) and it would have to offer mobile communication capabilities. Many efforts have been previously reported [7–9]. The current version of the DIA-

BTel PU tackled some of these issues implementing the system on a commercial hand-held computer. But the state-of-the-art technology available when the DIABTel project was born restricted the project ambition and limited the final PU usability. Additionally, the reliability of the pocket computer selected (HP-200LX) showed significant unexpected technological constraints in comparison with the commercial system. These reliability problems produced the occasional crash of the PU during the pilot study when using an external modem connection. This caused the interruption of data communication and occasionally loss of data. The problem was managed before the pilot study was concluded by implementing an additional battery checking software procedure but the impact on the evaluation results is difficult to quantify.

As reported in other telemedicine experiences [22,26], a telemedicine system tends to increase doctors' workload in the initial stages. There are several reasons why the DIABTel system adds to the initial workload: (1) learning process for the new tool; (2) assistance to patients when they require technical support; (3) need for organisational and clinical protocol changes; and finally (4) system refinement tasks to adjust to the care team requirements.

One of the most critical issues in the feasibility pilot study was the installation and maintenance of the system in the hospital environment. Technical and administrative problems arose before the service was implemented and clinically operative. Technical personnel were required at the hospital to support users at any time. It was also crucial to train the users in order to exploit the functions of the telemedicine service to the full whilst minimising the required technical support.

Patients' compliance with the telemedicine protocols was higher than expected as can be inferred by the results showing the frequency of data communications with the MW. Furthermore, patients show at the end of the study a high acceptance of the system and assessed DIABTel as useful for therapy management; effective to improve patient–doctor communication; and helpful to increase their autonomy, without decreasing the required doctor supervision. However, the study also showed that patients were not exploiting all the available possibilities for more direct and frequent communication with doctors as the option of text messages was not greatly used. This fact can have several explanations such as the difficulty to change in a short time the traditional doctor–patient communication in which patients adopt a passive role and do not behave in a more interactive manner.

As it was expected, physicians performed more therapy adjustments during the DIABTel period, demonstrating that telemedicine can help to face promptly undesired metabolic control situations. The therapy changes decided by patients were similar in both periods.

A cost-benefit evaluation of the use of the telemedicine system in clinical routine is a very difficult task [26]. This analysis requires a long-term study and the evaluation of all changes and potential improvements attained for the patients, caregivers and healthcare organisations by the use of the new telemedicine procedures. On the other hand, this type of experience implies an important effort and resources expenditure to set up and maintain the system. In the DIABTel pilot the evaluation was scheduled within a 2 years project and the system was running at the hospital during 17 months. A 3-month period was required for technical verification and testing with volunteer patients and the last 14 months were used for the clinical experience described in this paper. During all the pilot study clinical and technical people were assigned at the hospital and system developers were also involved in the technical maintenance and usability evaluation tasks.

6. Conclusions

Home telemedicine and telecare services are providing innovative solutions in the effective treatment of chronic patients. In diabetes care, telemedicine can give people the tools they need to take better control of their illness. This paper has presented a complete telemedicine system devoted to diabetes care and the experience of its use in clinical routine. The pilot study carried out with the DIABTel telemedicine system has shown

the feasibility of the system in clinical routine usage and its potential benefits for diabetes care. These benefits over conventional methods are as follows: (1) the increase of the quality and quantity of the information collected by patients affording a better decision-making process for doctors and patients; (2) the improvement on the number of therapy adjustments to be performed by doctors; (3) a better physician–patient communication procedure; and (4) the positive trend of the impact of the system to enhance the metabolic control of patients.

The Web-based access to the MW is one of the main aspects for development in the near future. Use of the Web will aid co-operation between the components of the care team (diabetologists, nurses, specialists, general practitioners) in order to achieve a continuous and shared care process [27]. An example of the current use of this developing DIABTel feature is the acquisition of eye fundus images at the primary care centre for viewing at the hospital, through the Web-based service. These images may then be used by ophthalmologists for patient retinopathy follow-up. The final goal would be to provide an integrated tool for all parties involved in the diabetes patient care at any level (hospital or primary care), with the patient fully integrated as a member of this team to gradually empower him to manage his disease.

The rapid growth and development of information technologies during recent years in the areas of mobile computing, computer-telephony integration (CTI) and mobile Internet has shaped a new concept of PU. Today the seamless integration of available technologies can build a more universal and ubiquitous telecare service. At present the research team is developing a multiaccess server to implement new access methods both for patients and doctors. This will complement the daily care of diabetic patients, as well as their education and shared care between professionals [28]. This 'virtual diabetes disease management centre' integrates a full range of inexpensive and widely accepted information technologies (Web, GSM, palmtop, CTI, etc.) offering users a more universal, easy-to-use, on-line and cost-effective access to telemedicine and information services. This work is currently funded by the European M2DM Project [29].

The conclusions and the clinical impressions drawn during the pilot study establish the relevance of DIABTel as a potentially important tool in the intensive management of diabetes. The next step is to extend the study to an increased number of people and to other patient groups (newly diagnosed patients, pump treated Type I patients and pregnant patients) to continuously advance in the creation of new telemedicine diabetes care procedures. The tremendous impact of the new information technologies will allow integration of disease management, quality assessment, cost-effectiveness and education through telemedicine in order to deliver a better quality of diabetes care.

Acknowledgements

This work has been partially funded by the Spanish Research Grant CICYT SAF98-0170 'DIABTel' and by the Fundació Marató TV3 Research Project 'OPTIDIAB'. LifeScan also supported the pilot study and provided Glucose Meters. The authors wish to thank Francisco Campoy for his support of the pilot study.

References

[1] W.K. Waldhäusl, Finally we have arrived in a new millenium, Diabetologia 44 (2001) 1–1.
[2] A. de Leiva, P. Lefèbvre, J. Nerup, European dimension of Diabetes Research, Diabetologia 39 (1995) (EASD News) 5–11.
[3] The Diabetes Control and Complications Trial Research Group, The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus, N. Engl. J. Med. 329 (1993) 977–986.
[4] American Diabetes Association, Clinical practice recommendations, Diabetes Care 22 (Suppl. 1) (1999) S1–S114.
[5] P.Z. Zimmet, Diabetes epidemiology as a tool to trigger diabetes research and care, Diabetologia 42 (1999) 499–518.
[6] E.R. Carson, S. Andreassen, D.A. Cavan, E.J. Gómez, Computers in diabetes—an introduction, Comput. Methods Progr. Biomed. 62 (3) (2000) 153–155.
[7] EURODIABETA Partnership, Information technology for Diabetes Care in Europe: the EURODIABETA initiative, Diabet. Med. 7 (1990) 639–650.

[8] E.J. Gómez, F. Del Pozo, M.E. Hernando, Telemedicine for diabetes care: the DIABTel approach towards diabetes telecare, Med. Inform. 21 (4) (1996) 283–295.
[9] E.D. Lehmann (Ed.), Application of information technology in clinical diabetes care. Part 1 Databases, algorithms and decision support, Med. Inform. 21 (1996) 255–374.
[10] E.D. Lehmann (Ed.), Application of information technology in clinical diabetes care. Part 2 Models and education, Med. Inform. 22 (1997) 1–118.
[11] E.J. Gómez, F. Del Pozo, M.T. Arredondo, Telemedicine: a new model of health care, Int. J. Tech. Manag. 1 (3-4) (1999) 374–390.
[12] E.H. Shortliffe, Health care and the next generation Internet, Ann. Intern. Med. 129 (1998) 138–140.
[13] B. Pal, Internet helps communication between doctors and patients, Br. Med. J. 320 (2000) 59.
[14] F. Del Pozo, E.J. Gómez, M.T. Arredondo, A Telemedicine approach to diabetes management, Diab. Nutr. Metab. 4 (Suppl. 1) (1991) 149–153.
[15] A. Billiard, V. Rohmer, M.A. Roques, M.G. Joseph, S. Suraniti, P. Giraud, J.M. Limal, P. Fressinaud, M. Marre, Telematic transmission of computerised blood glucose profiles for IDDM patients, Diabetes Care 14 (1991) 130–134.
[16] K. Ahring, J.P. Ahring, C. Joyce, N.R. Farid, Telephone modem access improves diabetes control in those with insulin-requiring diabetes, Diabetes Care 15 (1992) 971–975.
[17] M. Levy, P. Ferrand, V. Chirat, SESAM-DIABETE, an expert system for insulin-requiring diabetic patient education, Comput. Biomed. Res. 22 (1989) 442–453.
[18] A.M. Albisser, R.I. Harris, S. Sakkal, I.D. Parson, S.C.E. Chao, Diabetes intervention in the information age, Med. Inform. 21 (1996) 297–317.
[19] R. Bellazzi, C. Cobelli, E.J. Gómez, E. Hernando, G. Nucci, A. Riva, R. Corcoy, G. d'Annuncio, A. de Leiva, S. del Prato, S. Fiocchi, V. Koivisto, A. Maran, M. Stefanelli, Telematic management of insulin dependent diabetes mellitus: the technical and clinical infrastructure of the TIDDM project, Diab. Nutr. Metab. 11 (1) (1998) 67–67.
[20] L. Abrams, $28 Million DHHS Grant for Diabetes Care goes to Columbia University, Telemed. Today 16(7) 2000.
[21] M.E. Hernando, E.J. Gómez, R. Corcoy, F. del Pozo, Evaluation of DIABNET, a decision support system for therapy planning in gestational diabetes, Comput. Methods Progr. Biomed. 62 (3) (2000) 235–248.
[22] E.J. Gómez, F. del Pozo, E. Ortiz, N. Malpica, H. Rahms, A broadband multimedia collaborative system for advanced teleradiology and medical diagnosis, IEEE Trans. Inf. Technol. Biomed. 2 (3) (1998) 146–156.
[23] J. Cermeño, R. Corcoy, E. Brugués, E. Hernando, E. Gómez, A. de Leiva, Feasibility of Diabtel in the follow-up ot Type 1 diabetic patients, Diab. Res. Clin. Prac. 50 (1) (2000) P811.
[24] E.J. Gómez, F. del Pozo, M.T. Arredondo, M. Sanz, E. Hernando, A telemedicine distributed decision-support system for diabetes management, In: Proceedings 14th IEEE Annual Conference of the Engineering in Medicine and Biology Society, IEEE Press, New York, 1992, pp. 1238–1239.
[25] S. Montani, R. Bellazzi, L. Portinale, G. d'Annunzio, S. Fiocchi, M. Stefanelli, Diabetic patients management exploiting case-based reasoning techniques, Comput. Methods Progr. Biomed. 62 (2000) 205–218.
[26] J.M. Mitchell, P.J. Robinson, C. Seiboth, B. Koszegi, An evaluation of a network for professional development in child and adolescent mental health in rural and remote communities, J. Telemed. Telecare 6 (3) (2000) 158–162.
[27] S.F. Dinneen, S.S. Bjornsen, B.R. Zimmerman, C.A. Gorman, J.B. Knudsen, R.A. Rizza, S.A. Smith, S.C. Bryant, Towards an optimal model for community-based diabetes care: design and baseline data from the Mayo Health System Diabetes Translation Project, J. Eval. Clin. Pract. 6 (4) (2000) 421–429.
[28] M.E. Hernando, E.J. Gomez, A. Garcia and F. del Pozo, A multi-access server for the virtual management of diabetes, In: Proceedings ESEM 99 (Fifth conference of the European Society for Engineering and Medicine) (1999) 309–310.
[29] E. Hernando, E.J. Gómez, A. García, A. Jalón, R. Bellazzi, S. Montani, F. Ortiz, J.M. Viejo, Deliverable 5: Technology, services and systems specifications, ed. E. Hernando (Project M2DM: multi-access services for the management of diabetes mellitus UE. IST-1999-10315, Brussels, 2000).