Computerising a Guideline for the Management of Diabetes

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Summary. This paper reports an experience of computerising a clinical guideline for the management of non-insulin-dependent diabetes mellitus (NIDDM). The guideline, designed by the European NIDDM Policy Group is being used in a National Programme for Diabetes supported by the Portuguese Ministry of Health, who is keen to supporting its widespread use by general practitioners, namely in computerised form. The paper presents the main characteristics of the prototype that was implemented within the European project Prestige, and was developed according to the Prestige Protocol Model. The model is briefly described, together with the generic architecture that supports it. Then the main design decisions of the prototype are explained, regarding the modelling of a general practitioner workflow during a typical consultation and the user interface, two key issues for obtaining acceptance from the users. The limitations of the system are discussed and a number of directions are outlined in order to circumvent such limitations, and broaden the scope of applicability of the system.

Keywords: Clinical Guidelines, Clinical Protocols, Diabetes, Electronic Patient Record, Clinical Information Systems

1. Introduction

Non-insulin-dependent Diabetes Mellitus (NIDDM) is a common chronic disorder requiring, from the doctor and the diabetes healthcare team, comprehensive knowledge and time and a two-way collaboration with the diabetic patient. From the initial diagnosis to treatment and follow up throughout the patient lifetime, the utilisation of guidelines is expected to lead not only to better care plans for the management of diabetes in the different care settings, but also to improve the communication between primary and secondary care, a widely recognised need expressed not only by physicians and healthcare authorities, but specially by the patients.

In Portugal, provision of healthcare services is mainly dependent on a National Health System. The country is divided into seven Health Regions directly dependent from the Ministry of Health. The use of protocols for continuous quality development and the quality assessment of care are priorities of the Regional Strategy of Health for the years 1998-2007.

The Ministry of Health has a National Programme for Diabetes (a common health problem with 3% of prevalence and more than 10% of burden in the National Budget for Health) and is committed to the continuous quality monitoring of diabetes care, using the DiabCare Qnet framework [1]. This programme adopted the St. Vincent Declaration, which defines as general goals for diabetic patients a) Sustained improvement in health experience and a life approaching normal expectation in quality and quantity; and b) Prevention and care
of diabetes and its complications by intensifying research efforts. Moreover, the Ministry of Health has also published the Portuguese paper version of the Desktop Guide for the Management of Non-insulin-dependent Diabetes Mellitus (NIDDM) published by the European NIDDM Policy Group (a hypertext version can be found in [2]), primarily aimed at general practitioners (GPs).

The Ministry of Health, is further committed to disseminate the use of the NIDDM guideline, by participating in the development of a computer-based protocol, based on the above mentioned Desktop Guide, together with related technologies, and to implement educational tools for patient empowerment. This decision is in line with the identification of the computerisation of clinical guidelines and its integration with electronic patient records, as one of the most promising areas for the application of knowledge based technology in the Healthcare sector [3, 4].

The development of the NIDDM computerised guideline was carried within Project Prestige [5] through a tight collaboration of the Health Region of Lisbon and Tejo Valley, with other Portuguese partners in the project, namely CENTIS and UNINOVA.

The computerised protocol that was developed aims at supporting a GP to manage a diabetic patient, by providing a number of suggestions during the various visits that the management of such chronic disease requires. In all visits, the protocol suggests which information should be collected about the patient, it supports the diagnosis of the patient, and the set of activities that should be taken to control the disease, namely educating the patient, establish objectives of care, order routine and other tests, define treatments and refer the patient to specialists.

This paper reports the experience on the implementation of the NIDDM guideline into a computerised system and is organised as follows. Section 2 briefly describes the overall structure of the protocol and the Prestige Protocol Model in which it is based. Section 3 addresses its general architecture, including some features of the user interface. Section 4 presents a preliminary evaluation of the prototype system. Section 5 presents a discussion on the results achieved and the work that is further required.

2. Modelling a Guideline

A number of models have been recently proposed to model clinical guidelines [6, 7, 8, 9, 10]. Because they focus on different problems regarding the computerisation of clinical guidelines, ranging from more formal definitions of the process of decision making to more practical issues concerning the use of current technology (e.g. web technology), it is not easy to compare them (which clearly lies outside the scope of this paper). Given the context of our work in project Prestige, we naturally adopted the Prestige Protocol Model [6], that provides not only a formal specification of a guideline and but also the generic architecture required to turn such specification into a clinical decision support system. This model is outlined in this section, illustrated with the NIDDM protocol.

In the Prestige Model, guidelines to manage a certain condition (e.g. managing a diabetic patient) are represented by a Main Protocol. Any protocols can be decomposed in many components, which are themselves protocols. Hence a Main Protocol can be regarded as the root of a protocol tree in which the links represent part-of relations. A partial specification of the protocol we developed for the NIDDM guideline is shown in Figure 1 (the full protocol description is available in a deliverable of Project Prestige [5]), where components in bold are leaf protocols.

![Fig.1 The Structure of the NIDDM computerised Guideline](image-url)
The medical actions that are to be performed during the execution of a protocol are represented by medical acts, which borrow most of their semantics from the RICHE Act Management architecture [11] (e.g. act lifecycles - see below). Each medical act is associated to a leaf component of the protocol tree, and includes a number of attributes whose values are to be filled in during the execution of the protocol. Special protocol methods may be used to automatically fill in some of these slots, from the values of other attributes (e.g. to suggest a specific dosage of a drug depending on the patient condition, measured not only by patient findings but also from the past use of the drug). Figure 2 shows some of the attributes of the act that is associated with the leaf protocol "Obtain patient actual history".

Fig.2 Some attributes of Act TAKE_ACTUAL_HISTORY-DIABETES

Pathways for carrying out actions are modelled, in the Prestige Model, through the life cycles of protocols and associated actions. Instances of protocols and actions (e.g. related to a specific patient) follow a specified life cycle and have, at any point in time, a certain state. In general, a protocol becomes Relevant at a certain point in time, then it either becomes InUse or is Discarded. If InUse, it eventually gets Finished. Protocols may also be Discarded before being InUse and Aborted, while InUse. The acts associated to the leaf protocols also go through a life cycle. Typically they are first Established, then become InProgress and eventually Completed. In certain situations they can be Cancelled rather than becoming InProgress, and be Abandoned or temporarily Suspended while InProgress.

Care plans are therefore specified, in the Prestige Model, not directly by means of some flow chart, but rather through the specification of criteria for protocol state transitions. The transitions between all these states are thus governed by these criteria, whose evaluation depends not only on the current state but also on the state of the related components of the protocol. For example the Relevant criterion of a protocol component is evaluated as soon as its parent component (in the protocol tree) becomes Relevant, whereas the InUse and the Discard criteria are evaluated when the protocol becomes Relevant. A number of data items can be used to assess these state transition criteria. These include:

- the states of other components;
- the states of the associated acts;
- clinical data of the patient;
- items associated with the Healthcare environment. (e.g. availability of resources)

For example a component might become Relevant when a sibling component is Finished; a composed component is Finished when all its children are either Finished or Discarded. A leaf protocol component usually becomes Finished when the associated act terminates. A protocol that models a complex investigation procedure might become InUse if a certain clinical finding is observed in a patient. Finally the protocol associated to a clinical act might be Discarded if certain healthcare resources are not available. A specific example from the NIDDM protocol is the Relevant criterion of component "Patient Care Plan", shown below

Relevance Criterion: Protocol Obtain patient actual history finished OR Protocol Register test results finished

Such criterion is based on the assumption that the clinician should not even consider to jump to the treatment stage without having obtained either an actual history of the patient (i.e. since the last visit) or registering the results of some tests (ordered in the previous visit).

Whereas this is a rather general assumption, common to many other chronic disorders, there are some criteria whose specification is specific to NIDDM. For example, the InUse
criterion of the leaf component "Treatment Hyperglycaemia" recommends the treatment when the glycaemia level, in certain conditions, rise above specific thresholds, as shown below.

In Use Criterion: 
- Fast Blood Glucose > 110 mg/dl OR
- Random Blood Glucose > 144 mg/dl

Being a leaf component, this protocol has an act associated with it. At the moment, the specification of the act simply defines the kinds of data collected in each act, together with some recommendations (e.g. about Hyperglycaemia therapy) provided in a text box. In future it is expected that there will be some recommendations regarding the type and doses of the drugs (implementing the protocol methods assumed in the Prestige Model [6]).

Finally notice that the NIDDM computerised guideline, being targeted to GPs, is structured around the notion of a visit. As any chronic disease, diabetes requires a life long sequence of visits to the GP (and other health care agents) to keep the disease under control. Therefore, and according to the Prestige model, the main protocol is considered an iterative protocol, in the sense that, by default, after the completion of an instance of the protocol (i.e. a visit), another instance becomes immediately relevant.

### 3. System Architecture

The integration of the NIDDM application into a Healthcare Information System is done according to the generic architecture assumed in the PRESTIGE model, shown in Figure 3.

![Fig.3 The generic PRESTIGE Architecture](image)

The NIDDM protocol is stored in a Protocol Knowledge Base (the Run-Time Knowledge Base), where the specification of the generic protocol, namely its components and their state transition criteria is maintained. The data, which is specific to the patient, is stored into the Electronic Patient Record. Such data consists not only on specific patient properties (e.g. patient findings, clinical acts performed on the patient, etc.) entered by a user through the User Interface (Operational Front End), but also all the state transitions undergone by the instance of the generic protocol applied to the patient. These state transitions are triggered by a Protocol Manager, that takes into account both generic state transition criteria and specific patient data to evaluate, at run time, whether the criteria are met for the specific patient.

#### 3.1 User Interface

A key component of the above architecture is the Operational Front End. Such component not only takes into account specific organisation issues (for example, schedules of the organisation services, or whether a certain user is allowed to access specific patient data), by accessing an Organisation Manager, which includes an Act Manager and the access views defined in the organisation. More relevant to this paper is the set of recommendations that are triggered by the protocol manager and are presented by means of the User Interface. The major features of the application interface are now described with some examples from the NIDDM protocol.

The basic characteristic of the application interface is a tight integration between the visual component representing the protocol manager and the computer forms associated with the acts constituting protocol recommendations. These forms are used either for data entry of patient clinical details or to present textual recommendations to the user.
By means of different colours the user can see, at every moment, the current state of each protocol component or whether some data items are recommended or simply optional. For example, Figure 4 shows the data form (in Portuguese) corresponding to the act associated with the protocol leaf component “Obtain patient actual history”. Some of the data items (thirst, polyuria and asthenia) are shown in green to warn the user that they are mandatory in the context of the NIDDM guideline and the corresponding check boxes should be filled in.

Fig. 4 User Interface - A clinical act data form

The current state of each protocol component is also available to the user by means of a colour convention. In the same figure, the protocol components more closely related to the one being used (its siblings, i.e. the other components of the Patient Evaluation protocol) are shown in tabs below the user identification with different colours regarding whether they are Recommended (i.e. dark green), Optional (light green), Finished (in blue) or only Relevant but not yet recommended (grey).

The user may also have access to an overall picture of the states of all the protocol components by being presented the state of the whole protocol tree (see Figure 5). Again different colours mean different states (yellow for user aborted and red for abandoned).

Fig. 5 The state of an instance of the NIDDM Protocol Tree

4. User Validation

The Prestige application has so far been tested by one GP at the Health Region of Lisbon and a specialist in Diabetes at Hospital Egas Moniz. These clinicians were requested to use the application with real patient cases. The following aspects deserved a particular attention in the evaluation process:

- The system’s state transitions and the adequacy of recommendations to the user.
- The user interface
- The completeness and appropriateness of the data sets.

Clinical users have directly tested the user interface tools of the application for data capture and approved their design, with limited revisions. These have specially concerned the way data items are organised in the forms and the lack of facilities for entering repetitive data. For instance, when registering lab test results, for each test the system requests a reference date. Usually, several lab tests have been performed at the same date. Nevertheless the user needs to write the date for each one of them.

A few cases of lack of data validation have also been found, and corrected. For example, if the user specified that the patient had no retinopathy, all different types of retinopathy should also be set to not present (initially the system accepted that the user to subsequently specify the patient to have preproliferative retinopathy).

The system recommendations have been considered appropriate but it has been found that the system utilisation requires an amount of time usually not available in the routine practice of GPs. This is particularly the case of the first patient visit in which a large number of ‘acts’ are recommended and considerable amount of data is entered.

In some cases, specially concerning patient treatment, the way recommendations are presented to the clinician might need to be revised. At present, there is one act (and a corresponding form) concerning the treatment of every type of condition commonly associated with diabetes (e.g. a form to treat each of hypertension, dyslipoproteinaemia, hyperglycaemia, nephropathy, neuropathy, etc). If a patient suffers from several of these
conditions, the protocol will recommend its respective acts to be performed, which means the user needs to go through all of them one by one.

Data sets have been found quite complete and adequate. The very few data item reported as missing are actually not specified in the NIDDM guidelines, but were considered relevant by the user for characterising some associated condition.

5. Discussion

Specifying a protocol given some largely "imprecise guideline" is not a trivial task, as there are many ways of decomposing it into the different components. The logical decomposition of the management of a chronic disease does not always match the procedural steps that a GP takes during a consultation. Of course, a key (but not sufficient) issue to guarantee the use of a clinical healthcare system during a consultation is that this system allows a "seamless" interaction, not distracting the GP's attention from the patient.

Hence one has to analyse the steps taken during consultation by the GP, which was carefully done in the computerisation of the NIDDM guideline. In fact, assuming that the interaction of the GP with the system (both to enter data into and get support from it) is by means of forms (associated to clinical acts, in the Prestige Protocol model), then the work spent with computerisation of the guideline can be largely regarded as modelling a typical GP consultation. NIDDM specific advice occurs a) in the "tailoring" of generic acts (such as taking the history or observing the patient) to diabetes; and b) in the evaluation of protocol conditions that make certain protocols (and associated acts) recommended due to specific diabetic findings.

Our current implementation of the system imposes some constraints on the amount of tailoring that can be made. An important constraint is connected to the technology used, namely the rigid forms used to access the patient health record database. The current forms (developed with DELPHI PASCAL) are all compiled ones in order to speed up the user interface, and only minor changes depending on patient data can be performed dynamically (e.g. changing some colour fields). Later versions of the system will be implemented with more advanced technology, namely JAVA-XML, which will allow this increased dynamics, and the use of generic web browsers to view and interact with the forms.

As to the evaluation of protocol conditions, which largely determines the sequence of actions taken by the GP, one has to be very cautious in the design of the protocol. If the sequence imposed is too strict then it may be found too "unnatural" and lead to its rejection by the GP. If too loose, then little help is provided to the user that is mostly left unsupported. In the current implementation we leaned towards the second policy. We implemented a relatively flexible approach by seamlessly recommending (i.e. via the colour code scheme explained above) when certain acts should be performed but always leaving the GP in control: even if a protocol is not recommended the user may execute the associated act. The adequate balance has to be carefully obtained with the support of the GPs in the actual specification of the protocol.

As a whole, the implementation of the NIDDM computerised guideline has provided evidence that the Prestige Protocol Model is largely adequate to model the management of diabetes. Some difficulties to express criteria where circumvented by local adaptations of the currently adopted criteria language. More challenging difficulties will arise when trying to generalise the system to encompass other diseases also subject to guidelines.

Clearly one must be able to tailor a generic act (such as observing the patient) to more than one disease and that tailoring has to be dynamic (one may only decide to enter a certain protocol during the consultation). In some cases, and adopting a dynamic JAVA/XML technology, this will correspond to add the recommendation of the protocols being used (e.g.
to highlight to the user the characteristic findings of all the diseases being considered, so that they can be all collected. In other situations, this is more problematic, namely when there are potential interactions between the protocols (e.g. conflicting drug treatments, where drugs for one disease interact with drugs for another).

This aspect is already apparent, as mentioned above, in a single main protocol, as the treatment for different conditions associated to the same disease may interact. Nevertheless, the same problem is much more difficult to handle if two (treatment) protocols belong to different main protocols and hence are not analysed together to consider their interaction. This is a problem that was already apparent with the Medical Logic Modules proposed with the ARDEN syntax [12] that used a procedural representation in which the representation of knowledge is fused with the specification of a specific algorithmic function for an advice/reminder system. By adopting a more declarative approach to knowledge representation it should be easier to consider such interactions in the Prestige Protocol Model, but this is a problem still deserving further work.

The NIDDM protocol implemented has focused so far on its use by general practitioners. Future versions and extensions, should take into account other health care agents, namely the specialists the patient may be referred to, as well as the Patient that has a central role in the management of his/her diabetes (self-education, self-medication, etc). Such system will necessarily be accessible (via the web) from different sites where the different agents are, and its development will be much eased by the planned adoption of a JAVA-XML technology. Future collaboration of CENTIS, UNINOVA and the ARS should be able to carry out such development.

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References

NIDDM Management Protocol  
{ Main Protocol }  
Visit  { iterative component }  
Patient Evaluation  
  Obtain patient actual history  
  Characterise patient habits  
  Obtain patient past history  
  Obtain patient family history  
  Register test results  
  Patient examination  
  Evaluate objectives of care  

Diagnosis  
  Confirm Diabetes  
  Refine Diagnosis of Diabetes  
  Associated diagnoses / problems  

Patient Care Plan  
  Establish Objectives  
  Patient Education  
  Self-Monitoring  
  Management during illness  
  Order tests  
  Define Treatment  
    Define Nutrition Plan  
      Treatment Hyperglycaemia  
        (…and Intercurrent illness, Hypertension, Dyslipoproteinaemia, Hypoglycaemia, Nephropathy, Neuropathy, Associated disorders)  
  Patient Referral  
  Evaluate – Diabcare Form  

Fig.1 The Structure of the NIDDM computerised Guideline
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<tr>
<th>Associated Act:</th>
<th>TAKE_ACTUAL_HISTORY-DIABETES</th>
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<tbody>
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<td>Data Collected:</td>
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<td>Polyuria</td>
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<td>Asthenia</td>
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Fig.2 Some attributes of Act TAKE_ACTUAL_HISTORY-DIABETES
Fig. 3 The generic PRESTIGE Architecture
Fig.4 User Interface - A clinical act act data form
Fig. 5 The state of an instance of the NIDDM Protocol Tree