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A Computerised Guideline for the Management of Diabetes

Pedro Barahona*, Francisco Azevedo*, Mário Veloso ¤, Nuno Estêvão ¤, Rosa Gallego ‡
Universidade Nova de Lisboa and UNINOVA, 2825-Monte da Caparica, Portugal
¤ *Centis,* Rua dos Industriais, 7-2°-Dt., P - 1200 Lisboa, Portugal
‡ *Adm. Reg. de Saúde de Lisboa e Vale do Tejo, Av. Estados Unidos América, 77, 8°, P-1700 Lisboa*

Abstract. This paper describes an experience of computerising a clinical guideline for the management of Diabetes. This guideline is being used in a National Programme for Diabetes supported by the Health Ministry in Portugal, who is interested in supporting its use by General Practitioners. The prototype system was developed according to the Prestige Protocol Model that is briefly outlined. The main conclusions regarding practical design decisions are then reported, partly based on a preliminary evaluation of the system by GPs.

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 person. From the initial diagnosis to treatment and patient follow up throughout his / her life, the utilisation of guidelines are 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 Health Ministry. 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 Health Ministry 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 it has adopted 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 people with diabetes 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.

As a partner in project Prestige [2] through the Health Region of Lisbon and Tejo Valley, the Health Ministry is committed to use the computer-based protocol for the management of NIDDM developed in Prestige, together with related technologies, and to implement educational tools for patient empowerment. The computerised protocol that was implemented was based on the Portuguese version of the Desktop Guide for the Management of Non-insulin-dependent Diabetes Mellitus (NIDDM) published by the European NIDDM Policy [3].

This paper addresses the implementation of this 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 the general architecture.

Section 4 presents a preliminary evaluation of the prototype system. Section 5 presents the main conclusions and further work that is planned.

2. The Prestige Model

The NIDDM Protocol was developed following the Prestige Protocol Model [4]. Although it is not possible to describe this model in detail here, nor compare it with alternative models, this section presents a brief summary of the model, illustrated with the NIDDM protocol.

In this model, clinical workflow is represented with medical acts, borrowed from the RICHE Act Management architecture [REF], which are integrated within a main protocol. The protocol is organised as a tree, the acts being connected to the tree leafs, as illustrated with the NIDDM protocol shown in Fig.1 (the full protocol description is available in a deliverable of Project Prestige [2]. At this stage the protocol is aimed at supporting a general practitioner to manage a diabetic patient, in the various visits that the management of such chronic disease requires. As such, the protocol is structured around the notion of a visit, considered as an iterative protocol. The structure of the NIDDM protocol is presented below, with leaf components in bold (due to lack of space, most leafs of the Patient Care Plan are not shown).

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

The co-ordination between the different clinical acts performed in the management of diabetes is done through the states of the associated protocol leaf components. The state of each component goes through a life cycle: it becomes Relevant at a certain point in time, then it either becomes InUse or is discarded. If InUse, it eventually Finishes.

The transitions between all these states are governed by specific 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 Relevance criterion of some protocol component

is evaluated as soon as the 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 components 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 Relevance 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 jump into the specification of the treatment without having obtained either the actual history of the patient (i.e. since her 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, it has an associated act. At the moment, the specification of the acts 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.

3. System Architecture and the User Interface

The integration of the NIDDM application into a Healthcare Information System is done according to the generic architecture assumed in the PRESTIGE model. 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 data entered by a user through the User Interface, 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.

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 2 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 are shown in green to warn the user that she should fill in the corresponding check boxes).

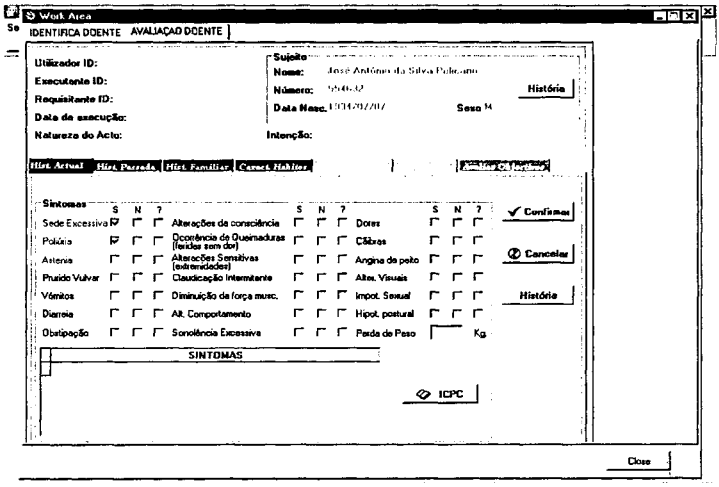

Fig.2 User Interface - A clinical act data form

The current state of each protocol component is also available to the user by means of a colour convention. In figure 2, protocol components of the patient evaluation 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 an overall picture of the states of all the protocol components by means of a protocol tree. Again different colours mean different states (yellow for user aborted and red for abandoned).

4. Validation and Demonstration Results

The Prestige application has so far been tested by one General Practitioner 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 are being corrected. For example, if the user specifies that the patient has no retinopathy, all different types of

retinopathy should also be set to not present (at present the system accepts that the user specifies subsequently 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 general practitioners. 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. Conclusions

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. These changes are being discussed in the consortium and there are plans to include them in later versions of the protocol model.

Specifying a protocol given some largely "unprecise 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. If too strict in following a formal management, the design of a protocol may impose a sequence of actions to the GP that is "unnatural" and lead to its rejection by the GP. If too loose, then little help is provided to the user that is mostly left unnatended. So far, the adequate balance as to be carefully obtained with the support of the GPs in the actual specification of the protocol.

The protocol implemented, diabetes, has focused in 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). Future collaboration of CENTIS, UNINOVA and the ARS should be able to carry out such development.

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References

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