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The Black Sea Tele-Diab System: Development-Implementation-Clinical Evaluation

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Abstract

This paper describes the application of the GEHR (Good European Health Record) architecture to develop a system to enable the storage and exchange of EHCRs (Electronic Health Care Record) of patients with diabetes, in the Black Sea area. The objectives of the Black Sea Tele Diab System (BSTD) were to develop and evaluate the use of a fully-computerised healthcare record system in a clinical setting, to promote the use of electronic data exchange of healthcare information and to provide a framework for the epidemiological study and monitoring of diabetes care.

1. Introduction

The BSTD system has been carefully constructed and developed to provide clinicians with a computer based healthcare record system and to promote the electronic exchange of healthcare information between clinicians and scientists in countries of the Black Sea area [1]. The project is part of the European Commission INCO Programme, (DG XIII) to provide support for Telematic Applications in Eastern Europe. The system was developed using a modular design and object oriented approach. It is based on the GEHR Architecture which was developed as part of the Advanced Informatics in Medicine programme. This provided the first complete data structure for EHCRs, key features of the architecture are:

- provision of a common data structure for electronic health care records taking into account the need to protect patient confidentiality and to reproduce a legally binding clinical record;
- ability to incorporate a wide range of data types i.e.laboratory data, photographs, biosignals;
- the facility to transmit medical records safely across telecommunications networks
- incorporation of mechanisms for translation of the information into different languages
- support for the process of clinical care and medical education.

GEHR also had a significant input into the work of TC251 (http://www.centc251.org/) and the recently published European EHCR standard (pr. ENV 13606). The technical requirements for the architecture (GEHR object model) are in the public domain (http://www.chime.ucl.ac.uk/).

The architecture is very comprehensive and has only been implemented in a few centres, given the limited time scale available for the project, the scope needed to be limited to a single disease area. Diabetes provides a good model for this since it is a chronic disease and is a major cause of morbidity, severe complications and premature death in all the central and eastern European countries. Standards for data collection and clinical care are also well developed, as primary prevention and prompt treatment can considerably reduce the incidence of complications.

The software for BSTD system has been developed in Microsoft Visual C++ and Access and is therefore fast and well integrated with the Windows environment.

2. Organizational Aspects

The project is the result of a collaboration between members of the BSTD consortium, made up of the following partners: University of Sheffield and University of Hull, UK; Research Institute and Diabetes Center, Greece; Institute of Diabetes, Nutrition and Metabolic Diseases, "N. Paulescu" and the Romanian Society Clinical Engineering and Medical Computing, Bucharest, Romania; Gorky State Medical University, Ukraine; Centre for Pathology, Chisinau, Moldova.

Software development has been carried out by the Romanian Society for Clinical Engineering and Medical Computing based in the Telemedicine Centre, Bucharest working with the Institute of Diabetes, Nutrition and Metabolic Diseases, "N. Paulescu", the Ambulatory Centre of Diabetes and the Centre of Diabetes, Hospital "Malaxa", Bucharest. It has been a major strength of the project that the derivation of the system has been based upon a comprehensive set of clinical requirements, further refined during the life of the project to provide a functional system for routine clinical practice. Regular consultation and discussion with all the partners has occurred during the formulation of the system, and the project software team has explicitly sought the advice of the clinicians on issues of the needs and of the semantic issues of constructing patient records using coded terms.

3. System development

The first step in the project was implementation of electronic links between the participating countries. This exceeded all the project participants' expectations in terms of utility of information transferred, distribution of prototype systems, user feedback and collection of clinical information. The project used the collection of data based on the WHO Europe DiabCare Basic Information Sheet (BIS) (http://www.diabcare.de) as a first model of the functional clinical requirements. It was considered that this would provide a sufficient level of detail to acquire and evaluate the system against the requirements of the GEHR architecture. The GEHR Object Model was examined to determine whether it would be suitable for the Diabcare BIS. A number of key issues needed to be addressed, including:

- the need to provide support for different countries and languages;
- mapping the fields on the sheet to the record items and groupings of the model;
- identifying the different types of content that would be needed;
- identifying the types of people and places that would need to be referred to.

Weaknesses in the model, identified by this analysis and other projects, were studied and a revised model (BSTDGOM1.0) was generated (www.telemed.ro/projects/bstd).

The GEHR structure is very comprehensive, data items being stored in a number of related tables that are held in a MS Access™ database. The software for the system has been developed in Microsoft Visual C++™ and when combined with the database, it provides an application that is fast and well integrated with the Windows environment. Development of the system has followed a stepwise approach with validation of the architecture and the incorporation of feedback from users at each key stage.

4. Overview of functional specification of BSTD system

There are five major work areas: patient records, reports, graphs, Diabetes Aggregated Data (DAD) and administration. Each of these contains a number of individual application/functions which are serviced by the relational tables that store the patient details, clinical measurements, doctors and user information. The Patient Records Function offers options for the management of the EHCRs (creation/correction/visualisation), such as: registration of a new patient and entry of the first record or sheet; the recording of a new sheet; the correction/visualisation of the sheet; the recording of data about the patient's death, etc. The System Administration Function allows: Definition of the health care facility; definition of persons as users or system managers; management of passwords and access rights for the users; definition of measurement units; limited customisation of the user interface.

Access control is based on a password mechanism stored in an encrypted form. The identification of the user is based on a unique number allocated by the BSTD system in the registration phase. The number includes the code of the country and the number of the centre. Within Eastern Europe it is our experience that data collection, analysis and transmission of data are considered more important than security and confidentiality. The GEHR architecture requires that each user has specified access and amendment rights. Also, individual users of the system are permitted rights regarding access to system administration functions.

The system recognises the following list of users:

- Physician authorizing the entry into the record – the physician who filled in the sheet;
- Physician legally responsible for the care of the patient at the time that this entry was made;
- Information provider – assumed to be the physician who filled in the sheet;
- Physician contacted – the physician with whom a face-to-face contact took place. The BSTD system assumes that this is the physician who filled in the sheet;
- Recorder – the actual staff member who entered the data into the BSTD system.

This approach allows good control of the recorded data, improving the security and also the integrity of data. One feature of the GEHR implementation is the preservation of the data in the original form. Any subsequent changes of the sheet are also preserved in the database. This provides a history of all the versions of a sheet and the name of the person responsible for the changes.

GEHR has a special group of structures regarding units. The BSTD system implements a flexible mechanism for units used for measurements. The list of possible units, the units used by default, the normal ranges and the conversion rules for units are established at the installation of the BSTD system and can be subsequently changed .through the "System Administration" function. The system allows the selection of the proper unit if it differs from the default displayed unit. When the data are committed to file, the BSTD system verifies if the entered value is within the normal range. If not, a warning message is displayed and the user decides if the value has to be corrected or not.

A range of data output formats are included with graphing functions and the ability to export data to other applications.

The DiabCare Aggregated Data (DAD) function provides automatic extraction of 16 items of aggregated data on all, or selected groups of patients according diabetes type, age group, durations of diabetes and year, for use with the WHO (Europe) quality care programs http://www.who.dk/

5. *Overview of technical architecture*

The basic components of the GEHR Architecture are: the electronic healthcare record (EHCR); the transaction; the health record item (HRI); the HRI collection; the heading.

The Electronic Healthcare Record is the electronic record for one patient on one system. The EHCR is the top level containment structure, and would be composed of one or more Transactions, together with some data enabling the record to be identified. The Transaction is the information recorded about a patient by a single author in one institution at one point in time. Examples of Transactions are: recording a clinical consultation, generating a report, recording a summary of care etc. A Transaction includes one or more Observations, optionally annotated by Headings. The Observation, comprising a name and a content value, is handled by the architecture construct Health Record Item (HRI). The HRI does not change the scope of the data. At the logical level a HRI can be regarded as the unit of information which can be obtained as the result of one specific measurement, question, observation, discussion, or other investigation mechanism. The Health Record Item Collection provides the mechanism for aggregating HRIs. It allows the scope (data subject) to be changed. The Heading provides a means of grouping or labelling combinations of HRI Collections/HRIs. Each of the above constructs has attributes defined in the BSTDGOM for capturing the necessary identification, content, and context of the Entry.

During system development modifications to the GEHR object model were necessary in order to satisfy the user requirements. An example is the inclusion of data relating to the patient's death, which is not covered by GEHR. In order to solve this problem we added an attribute to the Patient class: "Date of Death". If this were not present as an attribute at the outer levels of the record, the system would be forced to check through all the items and collections in the record to see whether the patient was still alive, which is not desirable. This supplementary attribute has been implemented as the "Date_of_Death" field in the Patient table. Also a specific structure has been created in order to record additional information (date of death, cause of death, comments). The BSTD system allows only the visualisation and the correction of recorded sheets for a deceased person, it does not allow a new sheet to be recorded.

An important feature of the system is the inclusion of clinical care protocols. Major studies in the USA and Europe have demonstrated that the incidence of diabetic complications can be considerably reduced by more intensive treatment and monitoring of patients with diabetes. There are guidelines or clinical care protocols, based on nationally or internationally agreed consensus statements, which can help the clinician with the management of patients. In spite of the availability of these, the standard of care varies considerably between countries and centres. Although part of this is due to limited availability of local health care resources, it is also due to the lack of access to information and poor communication. Studies into why clinicians do not use protocols have also shown that ready availability and ease of access are major factors. Clinical guidelines have been incorporated into the BSTD system. These have been developed by the Greek partner and are linked to data entry screens. They use are coded in html format so that they can be accessed from outside the system and can be linked to other sources of information on line.

6. *Conclusions*

The BSTD system is not yet complete but already its components are sufficiently well developed to demonstrate the concepts described by the GEHR architecture. Since the start of the BSTD project, the CEN pre-standard for EHCR has been published: http://www.chime.ucl.ac.uk/HealthI/EHCR-SupA There is much similarity between features in the BSTDGOM model and that proposed in the standards documents.

This presents the possibility of adapting areas of the existing BSTD model to include features of the CEN extended EHCR architecture that have not yet been incorporated, for example, improved access and distribution rights. The existence of commonality between the current BSTD model and the pre-standard should provide relative ease of transition. Examples include:

- The BSTD model makes use of the notion of Transactions, which corresponds well with the similar CEN notion of Compositions.
- As with the CEN EHCR architecture, the BSTD model incorporates a single subject of care and makes use of a wide variety of data types for the content of the records.
- The BSTD model necessarily allows for multi-lingual term sets and identifiable coding schemes. Although there will need to be some variation, this compares well with the equivalent CEN coding mechanisms.
- The BSTD software already makes use of a number of possible means of patient record identification and these can be used as Patient Matching Information for Extracts sent as part of messages of exchange.

Although the BSTD software and model allow for strictly controlled revisions and versioning of the information, the methodology is slightly different to that adopted in the current CEN pre-standard. It will be interesting to see how well the two relate as the pre-standard develops.

The system is currently undergoing clinical evaluation in diabetes centres in Romania, Ukraine and Moldova. In Romania and other Black Sea countries computer education in general has been a rather low priority among medical personnel for a number of years. It has been realised however, that this is now counter productive for long term quality of health care and so a training program has been started. These courses cover the requirements for electronic health records and use training material that has become available through the BSTD project.

The BSTD system is operational but lessons about how best be applied in a routine clinical setting still have to be learned. The concepts applied and learnt in Diabetes and will be generally applicable to other chronic diseases and medical disciplines.

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References

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