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HIGH PERFORMANCE ELECTRONIC HEALTH RECORD (EHR) IN DIABETES FOR COUNTRIES IN BLACK SEA REGION
PART 1

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Electronic Health Record (EHR) is a computerized medical record created in a medical unit that delivers healthcare. In recent years, massive amounts of data have become available for clinical research. These new sources of Big Data are defined as complex because they may be structured (*e.g.* EHR), semistructured (*e.g.* Clinical notes written by clinicians in the clinical settings) and unstructured (*e.g.* data from social networks, images, sensors). The key challenge for analyzing of the Big Data (a collection of large and complex data sets) is data integration from multiple autonomous disparate sources. But the main barriers in the healthcare systems, with focus for example in diabetes, for cohorts of data integration to turning data into actionable insight for improving outcomes, cost, and efficiency in healthcare through data analytic systems are:

- overcoming technological barriers to data capturing, storing, searching, sharing and analyzing (*e.g.* heterogeneous information systems and the lack of data dictionaries, standards and guidelines for the interoperability of the digital healthcare information);
- addressing privacy concerns and data security risks;
- aligning incentives to ensure access to data (in terms of data-evidence availability on-demand in decision making to perform daily work activities).

To use EHR technology and to address many of the above issues we developed the first successful EHR system under the banner of the EU project "*Black Sea Tele Diab*" *(BSTD)*, based upon the Good European Health Record (GEHR) and the CEN ENV 13606 standards for ITC development and on DIABCARE common dataset. The first part of the research develops upon architecture of the new EHR system. The second part of this study examines the System Administration function, Measurements units function and Main menu of the system. Finally, the third part of the paper describes clinical implementation and practical validayion of the EHR system. We conclude by suggesting future research directions.

Keywords: Electronic Health Records; Diabetes; Good European Health Record (GEHR); DIABCARE; Common Dataset; Black Sea Countries; Data analytics.

INTRODUCTION

Electronic health records (EHRs) has increased dramatically by adoption of the *Health Information Technology for Economic and Clinical Health (HITECH) Act*[1] (since the 2009 implementation). Utilizing a shared EHR improve the quality of care across differing patient populations and health care delivery models in USA[2]. Moreover, EHR integrated with advanced data analytics[3] can bridge the gap between the clinical care and the public health decision-making[4,5]. This enhance efficiency of the healthcare provided at the point of care, facilitates better performance measures for the benefit of patients care delivery and provides opportunities for administrative and clinical cost savings (*e.g.* eliminating duplicate lab tests). EHR, which will inevitably replace the paper record in the near future, is the key to the development, and ultimately the delivery of advanced data analytics solutions[6]. Unfortunately, the full potential of EHR big data research has remained largely unrealized[3]. The main challenges for the evolution of EHR are accessibility, interoperability and standardization.

In this paper we are mainly concerned with the practical aspects of developing, applying and using the EHR systems of maintaining and securing electronic patient records to better inform clinical decision-making. All data surrounding the patient care registered by healthcare professionals in daily clinical life (*i.e.* valuable data and useful data) can be used for exchanging health information between clinicians across an organization that delivers patient care. The main challenge with the approaches that enable the shift diabetes care toward preventive, predictive, personalized and participatory is integration of data originating from sensor based systems and EHR combined with smart data analytics methods and powerful user centered[7].

The European Committee for Standardization (CEN 13606, 2000) introduces EHR by a simple definition as "*a healthcare record in computer readable format*". The main aim of EHR is to provide substantial improvements to the quality and efficiency of healthcare services provided, especially for patients who suffer from chronic illnesses (*e.g.* diabetes). The Electronic Health Records data is recorded as structured data (*e.g.* any clinical measurement, lab results, etc.) and unstructured clinical notes (*e.g.* judgments made in the time of the healthcare delivery). Clinical notes (written by clinicians in the clinical settings) may contain rich and diverse source of information (*e.g.* individual behavior, finding, congenital abnormality, disease or syndrome, surgical notes and discharge summaries). Medication data can be in both structured and unstructured forms in EHR systems.

We developed the first successful electronic health record system. It was realized under the banner of the EU project "*Black Sea Tele Diab*" *(BSTD)*[8] on framework of EU research projects Inco-Copernicus. The system is based upon two standards: "Good European Health Record" (GEHR)[9] and "Electronic Communications" CEN ENV 13606[10, 11]. The project BSTD was coordinated by Sheffield University, Hallamshire Hospital (UK), with software quality led by The Hull University (UK). The system was developed by our Romanian team in Bucharest using a modular design and an object-oriented method[12, 13, 14]. The GEHR contains the set of concepts dealing with co-operation (patient records transfer) between healthcare providers around the care of a patient by standardizing the structure and the contents of EHRs.

WHAT KIND OF CHALLENGES DATA COLLECTION FACES?

The lesson that had to teach us during St. Vincent and Black Sea Diab Union initiatives implementation[15] is that voluntary-based data collection is not a self-sustainable solution[16]. The quality and the quantity of data collection strongly depend on the motivation of the health care professionals and the time available to generate databases voluntarily. The data is usually being copied from paper medical records. Often data errors were detected. The errors are due to both misinterpretation of the information in the original documents and mistakes in data entry. From the previous studies[15] we learned that there is no guarantee the adherence of healthcare professionals to data collection voluntarily because they are too busy in daily professional activity to worry about the data collection for specific purposes of outcomes and quality measurements. That was leading to lack of continuity in longevity of databases gathering. That was leading also to missing a continuous process of audit / outcome monitoring of what happens in real clinical practice based on prospective / retrospective studies for a longer period of time (independent of pharmaceutical industry trials).

The only way to successfully tackle these problems is by adopting electronic health care registries (EHR) through better access to data at the point of care. We need a more effective and more efficient approach for recording comprehensive and high quality data surrounded patient care than the voluntary-based approach of data collection for quality of care assessment. In other words, we need a "short cut" to quick and natural data collection and that is what EHR systems is all about. It is saving time by avoiding the double-entry method (*i.e.* data being copied from paper medical records into electronic (EHR) aiming healthcare quality assessment or for making various clinical studies).

DATA-DRIVEN RISK FACTORS

Combining knowledge- and data-driven risk factors in diabetes have been challenged us to think about the evolution of the ITC for health that may allow access to all data surrounding the patient care, valuable data and useful data for information extraction, feature selection and predictive modeling (classification, regression, patient

similarity). To improve the evidence for its effectiveness of health care by using outcomes and quality measurements is to introduce technological changes for EHR systems in terms of data completeness, trust in collected data to make the information credible (faithfully preserving the data as originally intended) and to provide data retrieval facilities (through an export function) for easier interface with data analysis systems. It is a very promising objective in terms of clinical outcomes measurement. It is also healthcare IT adoption for systematic collection of health information in digital format to create mechanisms to explore and support new visionary ideas to focus long term studies on the progression of diabetes and its complications.

Efficiency of the new technologies for EHR might be based on the plurality and diversity development of the interoperable EHR systems (to facilitate competition) making sure at the same time that we did not forget the running systems existing extensively in use (adequate solutions for import data from old systems into new systems should be envisaged). A competitive evolution gradually shape or improve EHR systems to become more efficient means of capturing patient data to electronic data exchange for healthcare and, simultaneously, for data feeding automatic analysis systems (*e.g*. an analytic platform).

However, in the case of EHR systems, the most common causes that generate problems to electronic data exchange and data integration are lack of data standardization. So, the main question raised was how an EHR system should be designed to address the systems interoperability to facilitate big data integration in order to satisfy health data automatic analysis needs?

To address these issues, at the foundation of the EHR system (that we have developed and described in this paper) are the standard dataset DIABCARE, the papers charts used in diabetes care and the architecture of the Good European Health Record (GEHR). GEHR is a project within the Advanced Informatics in Medicine (AIM) program which provides a set of rules and principles for electronic registries and existing networks[17]. The GEHR aims to develop and propagate a common architecture for computerized health records across Europe that can be used in clinical domains, countries, and computer systems[12].

This study has potential impact on the Web-based electronic health records. We think that this foundation (DIABCARE and GEHR) might be the concept to be applied to modern digital technologies of the electronic health care registries systems like Web-based resources and cloud computing for the exchange of electronic healthcare records in diabetes.

EHR SYSTEM BASED ON DIABCARE AND GEHR

TELEMATICS APPLICATIONS PROGRAMME
An Applied Research Programme of the
EUROPEAN COMMISSION. DG XIII C/E

This is a *success stories* project, initiated by the author of this paper, which created the first EHR system in diabetes in Black Sea area. The project was supported in the framework of the European Commission's Programme, Telematic Applications, DG XIII, for duration 1997 and 2000[12]. "*The BlackSea Tele Diab (BSTD) – diabetes computer system and communication network for Black Sea Region*" was a multidisciplinary research project with the main aim to promote exchange, by electronic means, of the healthcare information between clinicians and scientists in countries of the Black Sea area. It envisaged promoting medical informatics which provides a longitudinal electronic health record for each patient. It provides also a means for monitoring and measuring the outcomes and quality of diabetes care through which the care of patients may be enhanced (*e.g.* slow or potentially reverse disease progress).

The BSTD was built on an existing organizational framework provided by the Black Sea Diab Union initiative to develop a standardized software package (in the national languages of the Eastern Europe and New Independent States countries). By extensive implementation in research and medical-care centres the diabetes centres acquired sufficient opportunities to provide information to health policy-makers in diabetes care in region. The project had precisely specified objectives to promote outcomes and quality measurement in Black Sea region based on a new EHR system:

- Development of a state-of-the-art EHR system for basic information sheet, DIABCARE.

- Participants: 2 EU and 3 Black Sea region countries.
- Establish computer network for exchange of health information between diabetes centres in Black Sea area.
- Computer based clinical protocols.
- Transfer images / physiological signals.
- Assess cost/benefits of EHR and electronic communications.

The objectives and expected results of the BSTD had relevance in relation to the objectives and priorities described in the "*European Commission's Programme, Telematic Applications*". The current developments in Europe were also reflected as good as possible:

- For the storage and transfer of medical information and healthcare data between participating institutions, BSTD utilized a standard format for medical records based on the Good European Health Record (GEHR)[17,9].
- The diabetes dataset (fields and definitions) DIABCARE[18,19,20] has been used to allow a common dataset to monitoring of diabetes throughout Black Sea region.

The overall aims of the project were clearly defined and were associated with the St. Vincent work programme[19] to provide a strong basis to support public health research efforts directed to the prevention and care of diabetes in Europe. BSTD is also an interoperable EHR system which can help to apply a proactive approach to monitoring of patients with diabetes throughout their life.

According to GEHR, an EHR comprises on the one hand a root architectural component and on the other hand a record component established by original component complexes, data items and link items.

The key features of the GEHR architecture are:

- Provision of a common data structure for electronic health care records (EHR) 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, including laboratory data and biosignals.
- Facility to safely transmit medical records across telecommunications networks.
- Incorporation of mechanisms for translation of the information into different languages.
- Support for the process of clinical care and medical education.

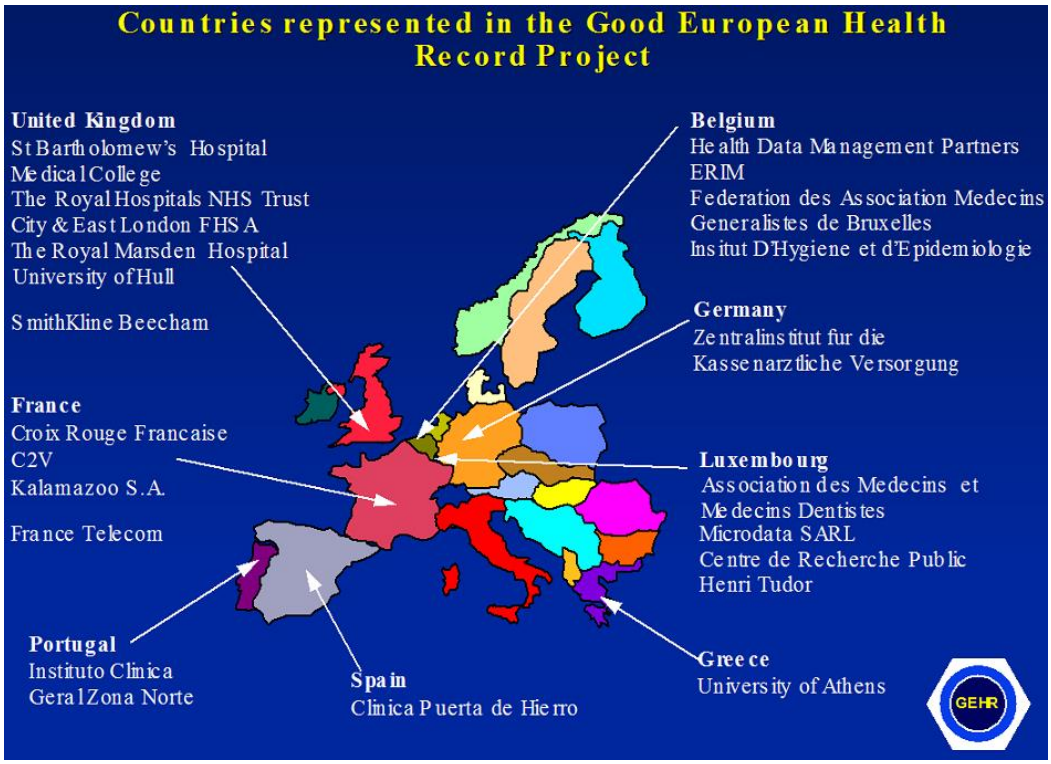

Figure 1. Countries represented in GEHR.

ARCHITECTURE OF THE NEW EHR SYSTEM

The BSTD system was developed using a modular design and object oriented method approach[21,8]. Also, it was developed based on the Good European Health Record (GEHR) Architecture. This step has never been skipped in the development of a successful system. Accurate data sourcing information is provided to the system's designer and available in the model's internal system for data recording. Figure 1 shows EU map with countries represented in the Good European Health Record project.

The CEN ENV 13606 defines in a generic way EHR-system components, their interfaces and behavior to provide a useful formalism for reconciling and re-using detailed data specifications across different use cases[22]. The CEN ENV 13606 consists of four parts: "extended architecture", "domain term list", "distribution rules", and "messages for the exchange of information". The meta-data model used by BSTD complied with WHO-Europe DIABCARE dataset (St. Vincent initiative). The system was written in C++, using Microsoft Access as a DBMS and including the following functions: Patient Records (EHCR), Clinical Protocols, Reports and Statistics, Graphs, Data Communication and System Administration.

There are strict rules that govern the users that can enter or access information that faithfully preserving the data as originally intended[10]. As well as BSTD is permitting analysis of the data, which can come from many sources using an XML exchange method. The international members of the BSTD Steering and Scientific Committees have been involved in work of direct relevance to the diabetes and the GEHR demands. The project Coordinator (*Dr. Nigel Harris, Sheffield University, UK*) has been involved in work of direct relevance to the BSTD project. The scientific qualification of the project Coordinator in diabetes has allowed him to create a coherent work plan, a management structure and a communication flow for acquiring the project objectives. The qualification of the our partner in charge for the deliverables to assuring the quality assessment (*Dr. Richard Dixon, Hull University, UK*) was appropriate to cover all the GEHR requirements because this partner was in direct connection with participation to the development of the GEHR project. Therefore, BSTD defined the best solutions for the GEHR demands:

- Developed as EU (AIM) project.
- Common European standard for electronic health care record.
- Supports wide range data types.
- Suitable for transmission by E-mail.
- Mechanisms for language translation.
- Open system for scalability.

The WHO Quality of Care and Technologies Programme is assured by the function of data export as a CSV data file that may be immediately accessed and analyzed to generate a full report with diabetes care outcomes that can help as basic information to improve diabetes care.

The BSTD system uses a slightly modified version of GEHR's Object Model[9, 17] *i.e.* the GOM_{BSTD} $V_{2.0}$. The extended component-based EHR reference architecture is mandated to meet any requirements through the health electronic record complete lifecycle. It is essential that inter-patient relations be well integrated into the electronic health care record (EHCR)[23]. Basic components of the GEHR object model (the UML conventions) for the BSTD system for the electronic healthcare record (EHR) are: transactions, the health record and items. The EHCR is the record for one patient on one system. It is the top level containment structure and is composed of one or more transactions, together with data to identify the record.

A transaction is information recorded about a patient by a single author in one institution at one point in time. Examples include 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, which comprises a name and content value, is handled by the architecture construct Health Record Item (HRI). In Figure 2 is shown the BSTD system basic components of the GEHR object model for transaction cluster.

The BSTD solution was only logical step forward to clinical diabetes data collection directly from the point of patient care. Of course, the EHR systems evolved through multiple generations (*e.g.* Web applications for EHR with servers' facilities to the Cloud that are being current in development). But the dataset, architecture and users interfaces developed and existing in BSTD might not differ for those of the very modern systems. Accordingly, the BSTD system components may be of important interest for the developers of today's electronic diabetes registries.

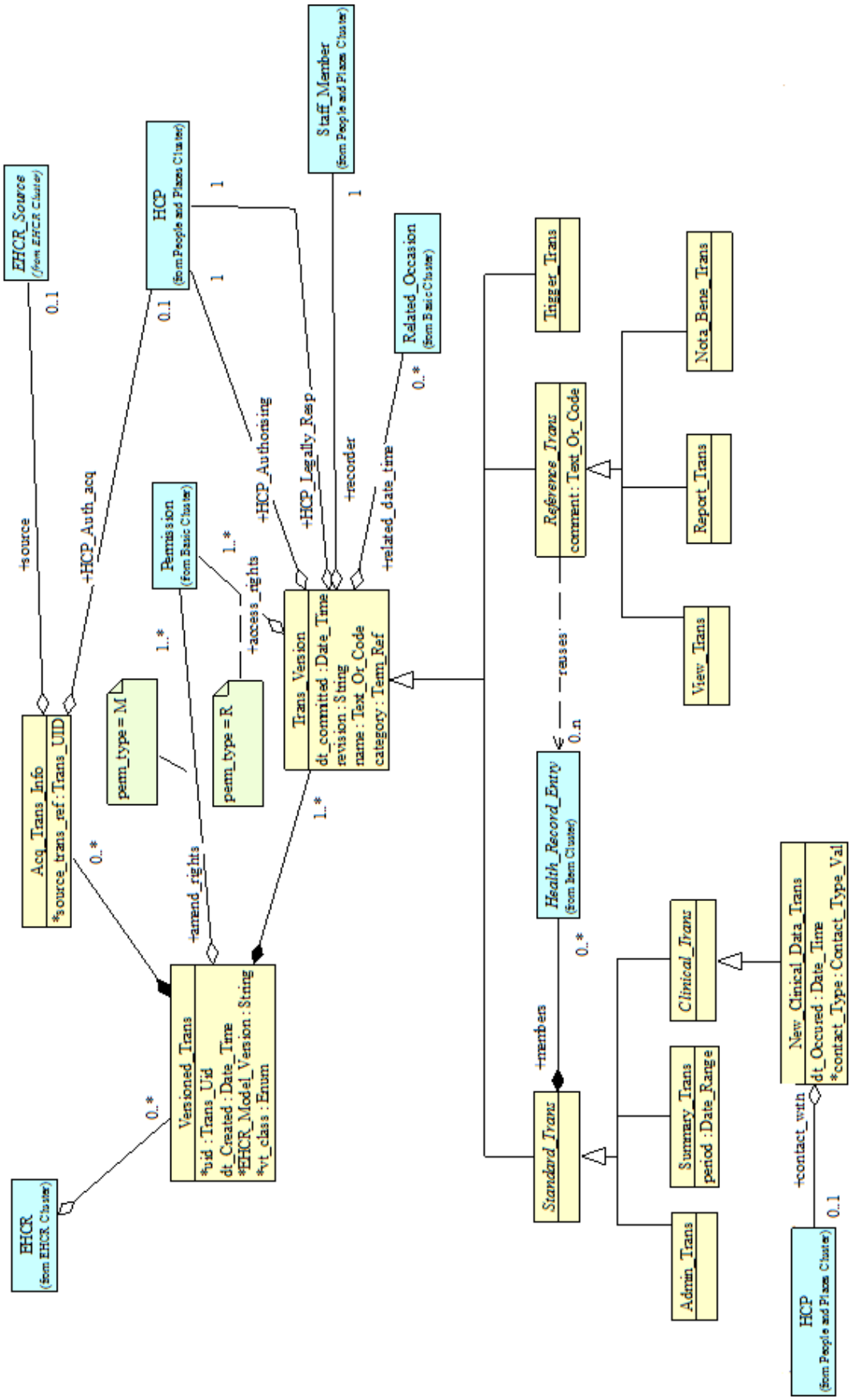

Figure 2. Transaction cluster GOM_{BSTD} $V_{2.0}$.

OVERVIEW OF TECHNICAL ARCHITECTURE

To support the functional framework outlined above, a technical architecture has also been developed. This was designed by analysis of the functional specifications for GEHR implementation and subsequent evolution of the BSTD technical architecture that would meet the clinical needs identified during consultation with clinicians, the main end users. GEHR structures the data on well-defined groups with clear correlation among them. This allows a good control of the access to the recorded data, improving the security and also the integrity of data. Exchange of data with other systems based on the same architecture is facilitated as well.

One of the advantages of the GEHR implementation is the preserving of the data in the original form. The subsequent changes of the data sheet (patient's file) are also preserved in the database. This allows obtaining a history of a sheet such as all the versions of the sheet, in correlation with date and name of the person who made the changes.

GEHR has a special group of structures regarding measurement units. The BSTD system implements a flexible mechanism for units used for items of measurements. The list of possible measurement 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 corresponding fields are filled, the BSTD system verifies if the entered value is within the normal range. If not, a warning message is displayed. The user decides if the value has to be corrected or not. The BSTD system allows the automatic conversion of units (*e.g.* mg/dl to mmol/l for blood glucose).

The identification of the user is based on the unique number allocated by the BSTD system in the registration phase. The number includes the code of the country and the identification number of the diabetes center. Also the patient can be retrieved in the database using the patient number used in the hospital, diabetic center, etc. The BSTD system allows the search of the patient based on search criteria including a combination of name, surname, gender, date of birth.

In the registration phase of a new patient into relational database of the BSTD, the system verifies if the patient is already recorded in the database. The search is based on the patient number, name, surname, gender, date of birth. If a record already exists in the database, the system notifies the user to decide if wish to continue or stop the registration.

HEALTHCARE CLINICAL PROTOCOLS

An important feature of the system is the inclusion of the clinical care protocols and clinical practice guidelines helping that the patient will be treated with a high quality plan. 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 clinical practice guidelines, 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. The BSTD system allows accessing the "Clinical Protocols" from the Main Menu Screen or from the "Measurements" and "Examinations" sections of the sheet. The home page of the "Clinical Protocols" function is presented in the Figure 3. There are implemented protocols for Diabetic Nephropathy, Diabetic Retinopathy and Diabetic Neuropathy.

The BSTD project focuses also on development of clinical care guide-lines through strengthening European scientific research on diabetes and to combat diabetes risk complications as key priority in public health policy on national and Black Sea countries level:

- Based on best available evidence
- Include clear criteria for evaluation
- Maximise benefits of limited resources
- Support St Vincent Declaration

Part of educational programme.

Figure 3. Clinical protocols with diabetes treatment options.

EUROPEAN SCIENTIFIC NETWORK

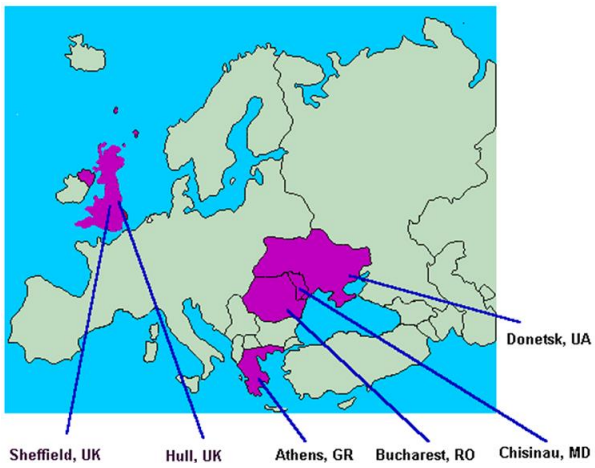

Figure 4. Black Sea TeleDiab – National Centres.

Figure 4 shows on the Europe map, the National Centres participants to the project. This project involved experts in the fields of diabetes, medical physics, computer science and epidemiology from University of Sheffield (UK), the project coordinator, University of Hull (UK), University of Athens, (GR), Institute of Diabetes "N. Paulescu" (RO), Romanian Society for Clinical Engineering and Medical Computing (RO), Academy of Science (MD) and Donetsk State Medical University, (UA).

The project participants who provided multidisciplinary expertise required for successfully approaching the electronic health care registry problem have carefully-prepared work plan to find best ways for cost-effectiveness procedures and standards to successfully tackle the problems by adopting electronic health care registries in diabetes. The Black Sea Diab Union action created an important opportunity for dissemination and exploitation the project results to demonstrate the efficiency and efficacy of the electronic health care registry for the diabetes prevalence alert and response strategies:

- Provides at Black Sea Diab Union organisational framework.
- Development of information network.
- Diabetes registers.
- Clinical standards.
- Education program.

Through this project a substantial research has been done to develop an Open Source (free software) diabetes information system (BSTD) and to clinically implementing into region.

Figure 5. BSTD has been clinically validated in region.

The BSTD system was carefully designed and developed to meet the requirements to encourage clinicians to abandon paper records in favor of a fully-computerized healthcare record. The system was released Open Source diabetes information system to promote the electronic exchange of healthcare information between clinicians and scientists in countries of the Black Sea area:

- Diabetes data set.
- Basic information sheet (BIS).
- Quality indicators and DiabCare Aggregated Data (DAD).
- Quality improvement programmes based on data-evidence.

Electronic registries and existing networks ensure continuous improvement in the quality of care and implementation of institutional public health knowledge for allowing the practical use of that knowledge on the field of diabetes:

- Support the development of health care databases.
- Provide support to management of patients with diabetes.
- Promote the exchange of medical information using the web.
- Improve the care of patients with diabetes (help identify most efficient use of resources).

CREATIVE INVOLVEMENT OF BSTD SYSTEM USERS

A robust functional framework was developed, based on literature research and by analysis GEHR deliverables to fulfill the following objectives:

- To enable detailed functional requirements that addresses the structure identified in the GEHR architecture.
- To provide the necessary linkage between the needs and expectations of diabetologists and practitioners and the key items of DIABCARE developed by the WHO Europe.

For the purpose of wide implementation in Black Sea region the BSTD system was built in four languages: English, Romanian, Greece and Russian. It was developed in Microsoft Visual C++ that facilitates an advanced user interfaces that will be compliant with the project usability requirements. The data base is in Access that allows to be well integrated with the Windows environment. The BSTD system implements the WHO/ Europe Basic Information Sheet, DIABCARE.

During the development process of the new system we found out the importance of involvement of the potential users for testing and validation of the system's functions for health data registration. We needed to excite the users about the EHR facilities and instill in them the passion to use the new system. The validation of the system in the process of development through a creative participation of users allowed a successful development in terms of the project usability requirements.

The feedback given on users' needs, were the essential elements for the required changes during prototyping EHR system to satisfy the needs of the implementation activities and to faster exploitation of the new system into clinical practice. It means full adherence of the health care users in using an EHR system for the complete and accurate health care information registration. BSTD project aims to develop and propagate a common architecture for computerized health records across Black Sea area, which can be used across clinical domains, countries and computer systems.

PRELIMINARY CONCLUSIONS

After the BSTD project was finalized and the EHR system was implemented as a diabetes register into clinical routine for data collection we had a visit of an expert in diabetes epidemiology from England (*Dr. Malcolm Roxburgh, was an expert for QCT*

office, WHO Europe, Copenhagen). The aim of that visit was a technical review of the BSTD implementation and in particular highlighting the scientific/technical achievements of the project, its contribution to the St. Vincent Declaration targets and its impact for improving diabetes care.

The scientific/technical review report of *Dr. Malcolm Roxburgh* has the following conclusions:

- The BSTD software project has succeeded in delivering a competent piece of diabetes clinic software, in step with emerging standards.
- The software is at a standard comparable with clinic IT systems marketed in Western Europe.
- There is a need to act reasonably quickly to move to wider implementation, and move beyond the scope of the research program.

The DG XIII selected the BSTD project among the best projects of the European Commission's Programme, Telematic Applications based on excellence through peer review, and provided support for our participation with a boot at the *MEDIFNO 2001, in London*. Our participation to that world IT for health event was a great success with good audience for our EHR software, BSTD system.

To be continued

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