B.I.R.O.

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WP12: Technology Transfer

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Technology Transfer Analysis

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Summary

Aims: The aims of Work package 12 of the BIRO project were: (i) To assess progress with respect to the Technology Transfer stated objectives of BIRO and (ii) To outline issues surrounding *evaluation and implementation by real users* of the BIRO software tools in Romania, Malta and Cyprus.

Materials and methods: WP12 has explored the practice of queering data and identifying *obstacles, risks and incentives* of the dissemination of sharing data in regions where no established diabetes register currently exists. As a project, BIRO is concerned with the collaborative creation of documents and software tools in order to extract and share data from multiple sources This process requires the collaboration of highly skilled technical experts who understand both the informatics technology used to implement BIRO software tools as well as the medical context in which these tools were need to operate. We report in this document the process steps used in installing the BIRO Box GUI and the use of this tool in creating and delivering structured data from semi-structured local data sources that can be queried and processed by BIRO statistical and BIRO reports programs. To test the BIRO tools we used samples of real data from Romania and Malta.

Results: This work package has resulted in specific gains made in the areas of data preparation (Data Extraction, Transformation & Load - ETL), the installation and use of the BIRO Box GUI Application and the export of various types of data. The processing of diabetes data (data integration, data storage and data usage) was very time consuming in the past, but with BIRO's modern technology and open source associated applications it is now much easier to collect and analyze data from various local sources. BIRO takes advantage of new Open Source technologies (free license and access to the source code) and involves the unidirectional migration of data, from local diabetes care locations to the BIRO regional data warehouse and to the central SEDIS for BIRO data analysis with various reporting tools and statistical applications developed in WP 8 and displayed with WP7 – Reports template. With respect to reporting of BIRO implementing at local and regional levels, selected issues, current limitations and possible improvements were formulated in WP12 analysis.

Conclusions: In this report we have demonstrated the broad scope of the BIRO project regarding technology transfer and issues surrounding evaluation and implementation by users of the software tools in Romania, Malta and Cyprus. The main conclusions are:

- Implementation of the BIRO technology involves the need for integration of medical and informatics profiles, with the purpose of overcoming the present profound divide existing between these.
- At national level BIRO should form part of the tools used in the strategic direction of a health care organization. We believe that the implementation of BIRO technology will improve the quality of diabetes care and capacity of health systems.

Keywords:

Health informatics, XML Schema, database adaptor, data connection, e-health applications, data integration, the extract, transform, and load (ETL), computerized medical records, validation rules, distributed systems, Diabetes, Data Mining, Templates.

Background

The activities of BIRO were based around 13 Work Packages. The objectives of Work Package 12 (Technology Transfer) were to test the feasibility of implementing the BIRO Information system and to provide feedback on the potential benefits and difficulties in transferability, bearing in mind the logistical and socio-cultural differences existing in BIRO countries.

The assessment was made through on field testing in three new member States, namely Malta, Cyprus and Romania.

SECTION 1. Local Setting State of the art

This section is organized as follows: We briefly discuss the local settings in three new Member States: Cyprus, Malta, and Romania. For each of the three countries we discuss details about:

- The diabetes health care management;
- How is data defined (data dictionary, items, minimum dataset, standards), Information systems, and
- Users

This is an overview of common situations in the collection and management of diabetes data, particularly in the framework of New Member States.

State of the art in Cyprus

Cyprus is the third largest Mediterranean island and it is situated in the extreme northeast corner of the Mediterranean. In 1974, the northern third of the island, (38%), was invaded and   occupied by Turkey. Since then, the southern part of the country has been under the control of the internationally recognized Cyprus government and the northern part under a Turkish Cypriot subordinate local administration supported by the presence of Turkish troops. All the information in this report is for the southern internationally recognized Republic.

Although a small country, Cyprus has an almost overwhelming cultural heritage. Wherever you travel, you will find ancient monuments and sites, churches and monasteries bearing silent witness to over 9000 years of civilization and history. Cyprus stands at the crossroads of Africa, Asia and Europe and this exotic mix is well reflected in Cyprus' cultural history.

The Cyprus landscape displays a great variety of styles. The coast has large open bays and precipitous cliffs and rocks. There are sandy beaches and shingle beaches. The precipitous mountains are mainly tree-covered to their peaks. The rest of the island is fertile hilly country. Cyprus claims 360 days of sunshine a year and it is well documented that one can ski up on the mountains in the morning and swim in the sea in the afternoon

The population is 855,000 with a growth rate of 0.5%; birthrate of 12.5/1000, infant mortality rate 6.7/1000 and life expectancy 78 years.

The religion of the Greek Cypriots is Orthodox and the official language Greek. Most people speak English as a second language.

Cyprus became a full member of the European Union in 2004.

The Medical Services in Cyprus

In 2005, as Cyprus joined BIRO, diabetes prevalence was known to be as high as 10.3% on the island.

Healthcare in Cyprus is provided by (a) a Public Healthcare System, which is means tested, and (b) by a Private Healthcare System, which is privately paid for. All people with diabetes are entitled to free medical care in the Public Healthcare Sector. This care is delivered at the five large hospitals and 32 rural health centres on the island. Care varies between the public and private sector and even between hospitals and rural centres, as there has not been an

agreed common framework of care and management of diabetes. Diabetes care is largely dependant on the individual doctor´s knowledge and understanding of the disease. Up to the time that Cyprus joined BIRO, no uniformed care existed largely because there were no national guidelines for the care of diabetes and no common framework within which people with diabetes would be looked after. The roles of the other healthcare professionals in a multidisciplinary team i.e. diabetes specialist nurse, dietician and podiatrist were not recognised and the doctors would work alone in the care of diabetes. Structured education was not available and each doctor would provide his own teaching including dietary knowledge. This is still largely done in the private sector.

Since joining the BIRO program and with the tremendous assistance of the partners, Cyprus has come a long way in the care of Diabetes. This is how it was done:
In April 2007 the first adult multidisciplinary run clinic on the island started operating at Larnaca Hospital. The team members are a consultant physician/diabetologist, a diabetes specialist nurse and a dietician. Other close associates include the ophthalmologist and the podiatrist (who only operates in the private sector at the present). Significant other associates e.g. nephrologists etc. are involved whenever necessary with the doctor referral system.

This clinic started operating as a direct result of the BIRO project and with the assistance of the partners, a common framework within which people with diabetes can be looked after was developed. This framework is in accordance with the international guidelines on diabetes care and follows the BIRO common dataset WP3.

The aims of the clinic are:
- Evidence based practice and evidence based clinical guidelines
- The education, training and empowerment of people with diabetes, leading to self-management.
- The prevention or delaying of the onset of complications
- The prevention of diabetes in the community through education and screening

The Larnaca Clinic started running as a pilot study for the Ministry of Health.   Three rural health centres of the Larnaca District (GPs) have also been working in collaboration with the Larnaca BIRO clinic within the same common framework collecting data according to the common framework.

The Ministry of Health has actively been supportive in the development of guidelines for the diagnosis and care of diabetes in the community. Further training for the care deliverers in diabetes has been organised and taking place. Healthcare providers in the field of diabetes have been travelling abroad, observing and working in diabetes centres along with colleagues, gaining valuable new knowledge and practical experience in the running of diabetes centres. Twenty-five nurses undertook the Certificate in Diabetes Care course delivered by a leading UK University, effectively qualifying as DSNs. All these people are preparing to take up their places in effectively looking after people with diabetes in the community and the Diabetes Clinics within a multidisciplinary team approach.

The (electronic) Diabetes Register

The electronic database register for Diabetes was created in April 2007. It was developed in Microsoft Access by the Department of Information Technology Services (DITS). It includes all the data items of the common dataset WP3 as well as some additional ones. Presently it is kept on a standalone computer at the Diabetes Centre in Larnaca Hospital. Data collected

is initially recorded manually and later it is entered into the electronic database. Every patient whose data is entered in the electronic database has given written consent for its inclusion and use. Entry into the system is password protected.

Projected Action Plan for Cyprus

The expansion of the care program in diabetes and the adoption of the BIRO-EUBIROD data collection program for the rest of the island will be taking place in stages over a period in the future. The three rural health centres in the Larnaca and Famagusta areas which have been collaborating with the Larnaca clinic have now got Diabetes Specialist Nurses working part time contributing vastly in both the care and education of people with diabetes and also in the data collection. The Paphos General Hospital on the west of the island has now started to collect data for the program.

The Projected action plan for Cyprus is as formalised by the prospective workplan described in Figure 1.
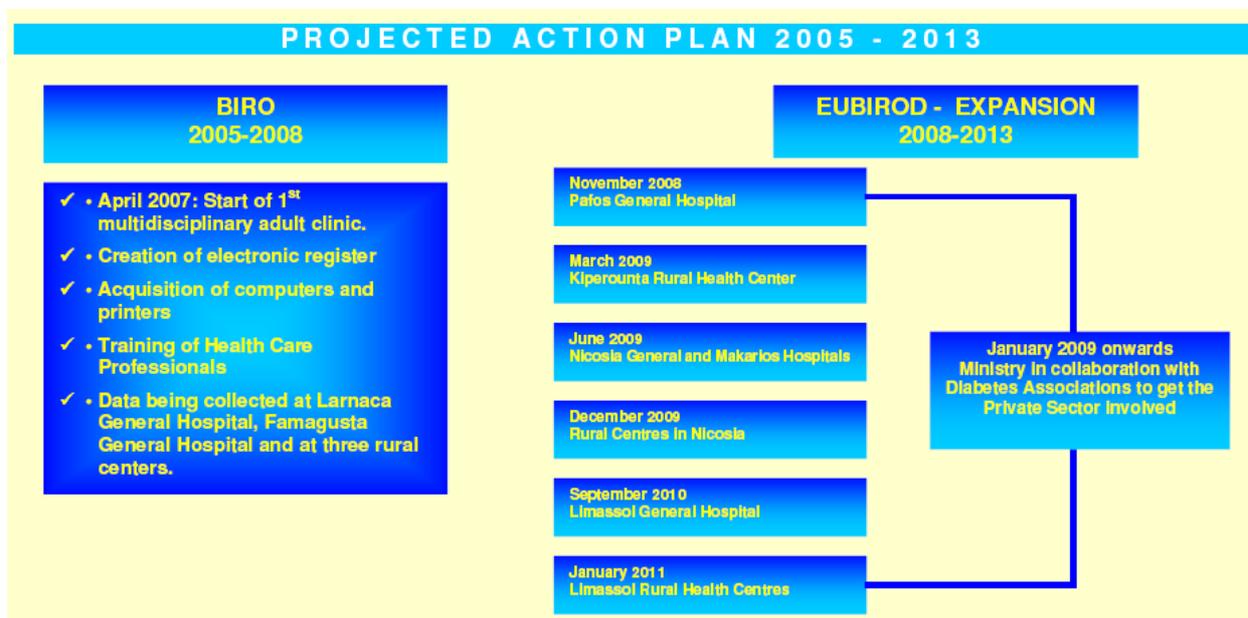
Figure 1: BIRO Action plan in Cyprus

The Electronic Healthcare Record System in Cyprus

The Intergraded Health Information System of the Ministry of Health came into effect in January 2007. It has now been installed in two hospitals on the island, one being the capital Nicosia´s General Hospital. The projected plan is that by 2013 all 5 hospitals and 32 rural health centres on the island will have this system installed and running. The program through the application of software supports medical, managerial and monetary operations in hospitals and health centres.

This system will store electronically the patients´ full medical records. It includes the following subsystems too: Patient administration, order management of goods, laboratories, billing,

prescription, radiology, coding of diseases/operations and procedures, blood bank, histopathology, stock control, health smart card and personnel management.

Added features include e-appointments via SMS or e-mail, both by the public and healthcare providers from other centres and cancellation or change of appointments by the public.

Presently the old system that exists in the rest of the hospitals and the rural health centres only allows for registration of patients, administration of events (inpatients and outpatients), appointment system and limited statistical data collection (e.g. births, deaths, causes of deaths etc.).

State of the art in Malta

Health care system

All residents in Malta have access to a health system providing preventive, investigative, curative and rehabilitative services. Health care is funded through local taxes, but is free at the point of delivery. A private health service is also available. A person who suffers from one or more of a specified list of chronic diseases (including diabetes mellitus) is entitled to free treatment irrespective of financial means.

The Government delivers primary health care mainly through eight Health Centres offering a full range of preventive, curative and rehabilitative services. Health Centers provide extensive preventive services, such as Well Baby clinics, Well Woman clinics, routine blood pressure and cholesterol checkups, smoking cessation clinics, screening for diabetes, and ophthalmological check-ups. There are also specialized preventive activities that are hospital-based (such as thyroid function screening for neonates).

The Government's Health Centre system works side by side with a thriving private sector and many residents opt for the services of private general practitioners and specialists who work in the primary care setting.

Secondary care and tertiary care are provided from a number of public hospitals, the principal one being Mater Dei Hospital, which has around 800 beds. Mater Dei provides a full range of secondary and tertiary medical services.

National health promotion activities are coordinated by the Department of Health Promotion. Several preventive programs are run on a national scale, such as the free immunization program, which covers a wide range of illnesses.

The main diabetes clinic in Malta is at Mater Dei Hospital. There are six other peripheral clinics. All work is coordinated through the central clinic at Mater Dei. Between them these clinics take care of 95% of all diabetic people in Malta and are therefore in an ideal situation for whole population studies on diabetes.

Over 1,300 new cases and over 12,000 follow up cases are seen yearly at the main diabetes clinic at Mater Dei and over 12,000 follow up cases are seen yearly at the peripheral clinics. All newly referred patients are initially assessed and managed at the main clinic and referred where appropriate for follow up at one of the peripheral clinics. Patients are seen routinely for

follow up visits approximately every few months or as often as necessary. The diabetes clinics in the peripheral centres are attended by peripheral health centre doctors; doctors or consultants from Mater Dei Diabetes Clinic visit the peripheral clinics for consultations. The diabetes clinic has a fully developed diabetes computerized management system and was one of the pioneers in the development of the St Vincent DiabCare program. The computer database has 23771 patients registered. The Diabetes clinic works in close collaboration with the Medical School of the University of Malta through which research into diabetes is coordinated. The present research interests of the diabetes department are the epidemiology of diabetes, coronary artery disease in diabetes, the use of computers for diabetes research and management and the study of nephropathy in families of people with diabetes.

The diabetes unit offers full ophthalmological, foot, obstetric, paediatric and educational services in collaboration with the appropriate departments. Routine eye screening is done either in the diabetes clinics by trained doctors or in the ophthalmic units at the central or peripheral clinics. Patients are referred to the ophthalmic units as required. A podology service, a foot referral clinic and a peripheral vascular surgery unit are available. An orthotics and prosthetics service is available. A weekly joint Obstetrics - Diabetes clinic is held at Mater Dei hospital. A Paediatric clinic is held at Mater Dei diabetes clinic every week. The children are managed by a paediatric diabetologist. The present dietetic service needs to be improved at present only two dieticians are working at the diabetes clinic at Mater Dei on a part time basis.

Patients with Type 1 Diabetes are given individual education together with patients and relatives. Group education programs for Type 2 Diabetes patients are held at the diabetes clinic at Mater Dei and periodically at the peripheral centres. Staff from the Diabetes Clinic Team contributes regularly to the educational program of the Maltese Diabetes Association held monthly. Members of the Diabetes unit are involved regularly in various radio and television educational programs aimed for the general public.

Periodic educational programs are co organized with the University for undergraduate and post graduate students. Periodic educational programs are held in various government and non government schools.

All patients under the age of 36 are provided with 2 blood glucose strips per day. Pregnant patients are given 4 strips per day. All patients with diabetes are entitled to free medications for care of their condition. All patients have easy access to laboratory and other investigative procedures as well as to regular ophthalmology, cardiology, nephrology, chiropody, dental and orthopaedic, psychology, social work and other services. Kidney transplant facilities are available.

Diabetes Information System

A diabetes information system is available at the main diabetes clinic at Mater Dei: data is either entered into the computer system directly by whoever is seeing the patient or written down manually and later entered into the system by a data entry operator. Entry is password protected.

Patients can be identified either by ID card Number, Passport Number or Surname and First Name. Any patient who has been registered on the hospital Patient Administration System can be accessed directly by the program. On initial entry the patient's Name, Surname, ID Card Number, Age and Sex are shown. Once the appropriate data has been entered, subsequent entries into the system will display in addition the Type of Diabetes, Waist circumference, Height, BMI and the number of years the patient has been diagnosed with Diabetes. This data will subsequently appear at the top of any screen opened during the patient's visit. Each screen allows entry of free text by the operator. When one enters data one has the option of creating a first clinic visit, a Follow up visit or a Yearly Review Visit.

Entry into the system allows access to a number of screens. They allow continuous follow up of the following characteristics:

1. Status of the patient. Visit Routine Parameters, Visit Type, Results of any Oral Glucose Tolerance Test performed, and the Clinical Status of the patient i.e. The Type of Diabetes if any, IGT, IFG, No diabetes, or Defaulter.
2. Clinic visit routine and drugs the patient is taking. This screen has four sub forms with the following data:
    - Date of Visit, Height, Weight, Waist. Circumference, BMI, BP, Fasting or Random. Blood Glucose, Hba1c, Urine analysis.
    - Current Diabetes Medications and Dosage.
    - Current Non Diabetes Medications and Dosage.
    -
    - Free text entry.
3. Patient Diabetic History. Year Diagnosed, Family History of Diabetes and Current Smoking and Alcohol Status, self monitoring blood glucose status, whether eyes and feet have been examined over previous year.
4. Symptoms related to Diabetes Complications. Peripheral neuropathy, intermittent claudication, Impotence, Postural hypotension, Angina, Autonomic Neuropathy, Current or Past Foot Ulcer or Gangrene.
5. Medical History. Any medical condition that the patient may have suffered from with the Year the condition was noted and Type of Management i.e. Medical, Surgical or Other. A sub form lists the current non diabetes medications the patient is taking.
6. Physical Examination. This screen allows the entry of physical examination data. A sub form data sheet lists the results of all previous physical examinations.
7. Complications. The complications of Diabetes and the Year noted.
    - Neuropathy. Any abnormal sensation, the presence of Diabetic Mononeuropathy, polyneuropathy, Amyotrophy or autonomic neuropathy.
    - Peripheral vascular disease. Diminished or Absent Foot Pulses, Ulceration or Gangrene, Bypass or Angioplasty, Above or Below Knee Amputation.
    - Nephropathy. Microalbuminuria, gross albuminuria, the presence of renal failure and whether the patient has had renal dialysis or a transplant.
    - Cerebrovascular disease. A history of Cerebral Stroke or Transient Ischaemic Attack and Year Noted.
    - Coronary Artery Disease. Angina Pectoris, Myocardial Infarction, Angioplasty or Coronary Artery Bypass Surgery.

- Retinopathy. Visual symptoms, History of Glaucoma, Best Visual Acuity, the presence of and grading of Diabetic Retinopathy, Photocoagulation therapy, and the presence of Legal Blindness.

9. Dietary advice. Date of visit, the Diet Type prescribed
10. Laboratory Investigation results. Lipids, Creatinine, Haemoglobin, White blood, Count, Platelets, and Electrolytes, Thyroid Function Tests, Electrocardiogram, X-Ray findings and results of any other tests.
11. Education topics dealt with and Name of Educator.

The system is very stable and broadly used, allowing a straight export of data to all major database formats. The system is capable of exchanging data between the Maltese database and the BIRO common dataset.

State of the art in Romania

Health Care System

Currently there is an estimated figure of over 500,000 diabetics living in Romania. Although the majority of individuals with diabetes have their first contact with a primary care doctor (family practitioner, internist, paediatrician, obstetrician, etc.) almost all diabetic patients are initially seen and regularly followed by a specialist (a diabetologist).

The Ministry of Public Health (MPH) coordinates, through Regional Health Authorities, and county offices, the public healthcare policy for all types of health units, public or private. MPH is responsible for public health, health policy, regulations, health programs, and investments in public health establishments. However, some ministries have their own healthcare network. The national health programs are administrated by a National Agency for Health Programs, in the framework of the Ministry of Public Health.

As in many countries, diabetes management is a systematic approach to detecting and treating diabetes using practice guidelines to provide the following: (i) systematic approach for clinical decision making in the treatment of type 1 and type 2 diabetes and its complications; (ii) consistent set of scientifically based practice guidelines that can be adapted by each diabetes centre, according its resources. Across Romania there are 40 diabetes centers; and (iii) identify appropriate criteria for therapies during three treatment phases: startup, adjustment and maintenance.

The human resource crisis in low-resource country is merely acknowledged. There is discussion among professionals and decision makers of possible solutions involving long-term human-resource policies for training and retention of required health workers, who face normally excessive workload and lack of upgrading.

Ministry of Health has in its program a higher involvement of primary care specifically trained and skilled in comprehensive first contact and continuing care of type 2 diabetes.

Romania has adopted action plans specifically for diabetes that also include primary prevention approaches. Furthermore, the Ministry of Health has selected the prevention of

type 2 diabetes as a focal theme for Romania in the first half of 2007. However, primary care providers need a carefully developed set of practice guidelines that can be realistically implemented and shown to be efficacious and cost-effective. Also, primary care includes health promotion, disease prevention, health maintenance, patient education, diagnosis and treatment of acute and chronic illness in a variety of health care settings.

Current approaches to policy and management of medical assistance for diabetic patients in Romania is based on the recognition of the benefit of near-normal levels of glycaemic control. It is well understood that a continuous relation exists between glycogenic control and the incidence and progression of micro vascular complications, as well as the adverse effect of hypertension and smoking on micro vascular outcomes. Few fundamental studies have produced a sharp attitude on the control of glycogenic goals, improving long-term outcomes in the diabetic population: the UK Prospective Diabetes Study (UKPDS)[8] and controlled clinical trials such as the DCCT[9].

Nowadays, any improvement in glycogenic control is seen as a means of preventing or slowing the progression of micro vascular complications, with potential benefits in terms of reduction of the risk of macro vascular disease. Maintaining glycogenic levels as close to the non-diabetic range as possible has been demonstrated to have a powerful beneficial impact on diabetes specific complications, including retinopathy, nephropathy and neuropathy for both the type 1 diabetes and the type 2 diabetes.

National diabetes programs have undergone clinical trials and implementation studies, favouring results leading to changes in the original design of diabetes management in Romania. Annually (usually in May), experts in diabetes from Romania and around the world are being gathered in the National Diabetes Congress, normally taking place in renowned university centres. This Conference is regarded as a high level meeting point, where many aspects of diabetes care and research are jointly discussed and networked more directly across disciplines.

An important contribution in diabetes research in Romania is carried out by the diabetes university centres, among which the Institute of Diabetes, Nutrition and Metabolic Diseases "Prof. N. C. Paulescu", the Romanian partner of the BIRO project, plays an important role.

Paulescu is a public body offering multidisciplinary clinical care for the patients of all ages and with all type of diabetes (60000 cases only in Bucharest).

The institute performs basic and clinical research activities in the field of metabolic diseases. Major areas of interest are: neuro-electrophysiology, nutrition, genetics, epidemiology and immunology related to metabolic diseases. As a university and research institute in diabetes, it is a very highly rated institution, with a very strong scientific basis, providing leadership in the collation of diabetes information.

The annual activity of the Paulescu Institute consists of medical assistance for diabetic patients in Bucharest (78800 diabetic patients), graduate and post-graduate training in Diabetes, Nutrition and Metabolic Diseases; and research in diabetes and metabolism,

immunology, genetics, epidemiology, electrophysiology, education and psychological support.

Diabetes information systems

In 1997, a set of programs written in Epi-Info were used for the first time to create a Diabcare database in Bucharest and 10 other counties of Romania. The St. Vincent Diabcare data collection service was initially organized through an e-mail network[10] linking university teaching with diabetes care centres (Bucharest, Brasov, Braila, Buzau, Craiova, Constanta, Galati, Suceava, etc.) through the same interface for data collection.

After this initial experience, three other successful diabetes information systems were created to exchange data across clinical care units. New interfaces were designed for health care providers, to directly interact with patients as a normal component of health care provision. The main problem of these applications was represented by the use of routine procedures that were not always maintained properly by clinical units.

The first successful medical record system was realized under the banner of the EU project "Black Sea Tele Diab" (BSTD), based upon standard e.g. the Good European Health Record (GEHR) and the CEN ENV 13606 on "Electronic Communications" and EU research projects e.g. Inco-Copernicus[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 using a modular design and an object-oriented method. The GEHR contains the set of concepts dealing with co-operation between healthcare providers around the care of a patient. Several concepts dealing with care plans and clinical pathways were also defined. The CEN ENV 13606 defines in a generic way EHR-system components, their inter faces and behaviour to provide a useful formalism for reconciling and re-using detailed data specifications across different use cases12-14. 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 (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[15].

The main objective of the project was similar to BIRO, i.e. enabling a quality improvement cycle of diabetes services through better monitoring of clinical care in Romania and countries of the Black Sea area. The Consortium created a diabetes health record system based on the GEHR model where diabetes was considered as a prototype for development of a model for chronic disease management. The "patient records" function allowed the registration of demographic information for a new patient, the recording of a new Data Sheet, corrections and the ability to search for and view a sheet.

Like any HL7's approach, the GEHR approach of BSTD deployed an object model defined according to the standards of the unified modeling language (UML), consisting of two parts: the concrete GEHR Object Model delivering the EHCR information container, and the GEHR

meta-models called Archetypes, to express the clinical content. Such architecture provided a common data structure for electronic health care records (EHCRs), taking into account ethical, legal, security and educational requirements.

A wide range of data types including quantitative results (measurements), semi-quantitative results (low, moderate, high) and qualitative results (yes/no) were also considered. The function "system administration allowed recording unique individual identifiers; tracking providers using the system; managing passwords and access rights for users; managing units and ranges used for measurements; managing the interface of the system; exporting data in CSV format; following clinical protocols.

The BSTD system was released as free software and underwent formal clinical evaluation in diabetes centers from Romania, Ukraine and Moldavia. It was finally implemented in clinical practice in few diabetes centres, including Paulescu and the Diabetes Ambulatory Centre and Diabetes Centre Hospital "Malaxa" in Bucharest.

Experience gained during development of the BSTD has been extended to develop the first Romanian Diabetes Register adopting the EHCR: SincroDiab. This software tool allowed central longitudinal management of diabetes episodes, shared across a range of providers.

Main objectives of Sincrodiab were: (i) To ensure quality and integrity of medical records at the clinical setting; (ii) to avoid redundancy and duplication of records; (iii) to develop an operational database including all episodes and procedures for diabetic patients. Functions similar to those in BSTD were also developed for SinchroDiab.

As an electronic healthcare record, SincroDiab represented a means of documenting the care process for an individual to manage information concerning the delivery of health care.

The software was written to deal with sensitive, personal medical data and complied with the major architectural features of the CEN standards: GEHR and prENV 13606 - Health informatics - Electronic healthcare record communication, and the codes of conduct of data protection legislation in Europe e.g. the Data Protection Directive[3].

The system was implemented successfully in clinical routine as free software. In 2006, a new product called "Hipocrate" was introduced by the Romanian Ministry of Health, followed by another product called Rodiab. Hipocrate was mainly used for printing prescriptions and therefore, has insufficient number of fields for BIRO analysis. Different approaches were introduced during the last years in Romania, raising a problem of consistency in the exchange of health records that may be resolved by a new standard.

Currently, the Romanian framework appears still too heterogeneous to allow a rapid introduction of common systems and interoperable services. The result until now has been poor use of health data. Health information systems in diabetes tend to be fragmented, inaccurate, cumbersome, untimely, and isolated. There might be substantial barriers for an extensive implementation of a common approach e.g. the one advocated by BIRO.

The vast majority of software development tools used in the diabetes sector today do not inherently support data exchange mechanisms. In generally software developers in the field in Romania typically have limited experience implementing data exchange protocols that would allow a rapid estimation of agreed indicators.

Furthermore, there are implicit business incentives for limiting the interoperability of different health information systems, leading to a diversity of attitudes and mix of skills that must be faced in the implementation of new protocols.

SECTION 2. Adaptation, implementation, setup and use of BIRO in Cyprus, Malta and Romania

This section discusses briefly the BIRO technology local implementation in three new Member States: Cyprus, Malta, and Romania. For each of the three countries we discuss the:

- Installation of the software
- Data export and the BIROBox
- Customized approaches
- Results of BIRO application through country tests

Technology Development and Workshop

Throughout the three years of the project, the main focus of technology development was the production of source code to allow the use of local data for the purpose of producing rapid statistical reports according to shared criteria.

A BIRO Technology Transfer Workshop was held on 17th of January 2009 at the BIRO final technology meeting in Bergen, Norway [7]. The approach was very practical, oriented to simulate actions that could be repeated on complete datasets after the installation of the software at each site. The workshop provided important suggestions on how to improve data processing procedures and user-friendly functionalities.

Installation of the software

The software was installed on notebooks owned by partner institutions, using a short user guide circulated by the Coordinating Centre. The required software, included the Java Runtime Environment, the PostgreSQL database, the statistical software R and the typesetting framework MikTek. Some adjustments were needed to define environment variables and install a BIRO local database for each test dataset.

A graphic user interface, in-house, was also installed. This is user friendly and allows direct field-mapping configuration of data in local databases to the BIRO Adaptor.

Adaptor and Stat Engine are already able to correct many mistakes in dataset in a way that is trasparent to the user.

This session was completed by each partner without particular difficulties.

Data export and the BIROBox

All partners contributed test data and each database was adjusted to allow for the export of a standardized BIRO database.

To configure the Adaptor, it is necessary to specify the SQL query that retrieves all the required data and exports it to one table. Commands are grouped into scripts. Programming

proficiency is necessary to undertake these steps and to write commands; this may represent a major drawback in the usability of the first version of BIRO.

Using the software local data can be exported to an XML standard BIRO file, based upon a predefined schema. All software has been written in the platform independent programming language Java, which can be installed on both Windows and Linux operating systems.

Participants experienced five different functionalities of the BIROBox:

1. User interface for mapping the file presented/created by the partners (csv file etc) to BIRO fields and their relative measurements/values. The box still needs fine-tuning, as results were only obtained after frequent breaks and a series of trial and errors. New additions of field values seem to be hard coded rather than read from a table. The end product contains records with one patient ID and his or her respective visits, where each file carries the necessary tags to identify region and date of upload as well as the period of time covered.

2. User interface to export data and produce xml files. Steps involved in exporting a subset of data from a database to XML are: connect to the database; specify the SQL to run to retrieve the data; specify the location of the flat file (XML); and data export. It was suggested that the run on the csv file be done in a way that records not fulfilling required criteria are stored to an error log file; this is better than having a program break and a restart with each and every problem encountered. Records may than be filtered by the location controller or be discarded if necessary. The idea that the results are saved in an xml file was questioned and discussed in detail and finally agreed as a possible solution.

3. Create BIRO database. This step was successful for those steps with no errors in the creation of XML.

4. Statistical Engine. This step was not carried out during the workshop.

5. Reports. Same as previous.

On installing the BIROBox, the following folders are also created:
- Folder to hold all xml files: one file per patient to include all visits and relevant data for that visit. Subsequent downloads of data will overwrite previous records and a copy may be taken to another subfolder.
- Folder to host local (country/region) database aggregated data. Sub folders will hold subsequent runs.
- Folder to host local (country/region) statistics results. Sub folders will hold subsequent results.
- Folder to host results that will be accessible by Biro central. Possibly shared/accessible by BIRO central.

The workshop highlighted the fact that the BIROBox may increase BIRO usability particularly through mapping from the original items that can be effectively visualized: each mapping can

display a help feature, with a description of fields being selected, which is helpful for users. However, the user needs to know in advance how to merge local files with the export, which implies an in depth knowledge of both the original and the BIRO common dataset. This implies that to some extent the user should also be medically proficient, to understand classifications and data coding. The motivation of users in the optimal use of this mapping tool remains an issue that must be resolved by identifying the ideal professionals to be targeted by BIRO for its continued use.

Fields mapping has been tested on a variety of data that are of common use in diabetes. Usability of the BIROBox has been tested directly on databases, looking at different measurements and ideal cut offs for classification for continuous variables, e.g. Systolic blood pressure (low: < 90 mmHg; normal: 90 mmHg – 140 mmHg; high: > 140 mmHg), or other situations in using counts with integer values, Boolean variables for true/false e.g. retinopathy). Inconsistencies have been noted in the configuration of fields mapping, compared to the BIRO data dictionary; these will be resolved in an improved version.

Further tests are required, based on different mapping scenarios, to better understand the needs of the prospective users.

Customised approaches

The nature of diabetes data is multidimensional and can thus become extremely complex. The BIROBox may not necessarily be adequate to satisfy all needs, particularly those of advanced users who may want to process many tables/databases at the same time; this would require sophisticated procedures to map/merge records before exporting them to the BIRO format. In these cases, the organization of local data may require using powerful third party tools independently of BIRO, made available either as a commercial solution (e.g. Business Objects) or open source software (e.g. Pentaho).

There may be inevitable problems in the extensive adaptation of the BIROBox to customized needs, as the BIROBox may not necessarily fit heterogeneous databases where clinical and administrative data can be simultaneously included to cover a wide spectrum of procedures. More collaboration between users and software developers is required to fill the gaps and sort out various issues that may arise.
It is always possible for users to deploy own solutions complying with BIRO specifications. This would not require using the BIROBox, and it would allow still contributing to the EU information system. This would still fit the scenario of a sustainable EU diabetes register, where different range of users may coexist and cooperate at the same time.

Results of BIRO application on data from Cyprus

The high level of compliance of the Cyprus data with the BIRO Common Dataset is a very special situation not found easily in European diabetes registers. In fact, the Cyprus dataset was developed precisely on the basis of BIRO definitions, and most fields can be directly used to compute BIRO indicators. The most challenging task during the BIROBox trial on Cyprus data was the set up of the connection with the local data source. The test dataset

provided, as well as the whole diabetes register in Cyprus, was developed using Microsoft Access.

Since no JDBC Driver for Microsoft Access was available at the Bergen meeting, the Microsoft Access dataset was directly exported as a CSV file (comma separated value), directly used as source for the BIRO Box. An alternative connection may be implemented using ODBC, so to establish a JDBC-ODBC bridge that would be implemented to link the BIROBox to the ODBC source.

After the correction of some errors in the format of the exported CSV file (e.g. missing dataset header, unexpected delimiter, etc), the BIROBox successfully read the data source. The Adaptor configuration phase, especially the file mapping between the local dataset and the BIRO dataset, was carried out very easily and rather quickly. The most problematic phase of the test application, i.e. the set up and connection with the data source was successfully passed.

Results of BIRO application on data from Malta

The Diabetes Computerized system uses a tailor made application in VB6 with an SQL2000 database backend. The diabetes dataset brought to Bergen consisted of a very small set of 100 records from the Diabetes Clinic Mater Dei Hospital in Malta. The dataset included all fields necessary for the BIRO project.

Certain fields required to be narrowed down to fit the BIRO specifications, as in the following cases:

BIRO Field: Retinopathy.
BIRO Coding: 0 (no), 1(yes) 2(Referral) accepted.
Malta Coding: Captures values for left and right separately.
Solution: If any of the fields (L/R) is filled, marked as positive.

BIRO Field: Diabetes.
BIRO Coding: 2(no), 1(yes) Accepted.
Malta Coding: 1,2,3 or unknown.
Solution: Need to specify if other values (3/Unknown) skipped/ignored or gathered with one value or the other.

BIRO Field: Oral Therapy
BIRO Coding: Five different values accepted
Malta Coding: Needs to be configured differently or grouped.

BIRO Field: Smoker
BIRO Coding: 0 (no), 1(yes) 2(x smoker)
Malta Coding: 0 and 1.

BIRO Field: Injections.
BIRO Coding: Number per day.

Malta Coding: Needs to be configured or calculated.

BIRO Field: Self monitoring.
Malta Coding: Field only added to database recently.

Apart from problems outlined above, the setup and creation of the BIRO database was successfully performed. A test run of the statistical engine denoted that many extreme situations can occur with a limited sample, indicating bugs in the R code that can be overcome with appropriate checks, and data inconsistencies that may occur by default in the creation of diabetes indicators from small samples. The particular application seems to suggest that minimal sample size requirements may be needed for the practical use of BIRO.

Results of BIRO application on data from Romania

The National Institute of Diabetes "Prof. N. Paulescu" in Bucharest presented a MySQL sample database with a single table taken from Diabcare data with 4,627 patients collected from few countries in Black Sea region. Data from multiple data sources had to be concatenated and converted to MySQL database format.

The first version of the BIRO adaptor (a software tool created by Perugia University) is connected to the source database and exports data from this local database to an XML file. This follows the BIRO specific data models, or "schemas". It is written in the platform independent programming language Java.

The steps involved in exporting a subset of data from a database to XML are:
- Connect to the database
- Specify the SQL to run to retrieve the data
- Specify the location of the flat file(XML)
- Export the data

In this case the Adaptor was used in its character-based version, successfully connecting original data to the database. Once written, a local configuration file was run in a completely automated way, outputting the XML file, which was then exported to the BIRO central database.

Note: Data from many data sources had to be concatenated and to be converted to MySQL database format.

The exporting of data from the database to XML is an offline process (Figure 3).

Figure 2: BIRO adaptor, the export of data in the database to XML file.

Once written, a local configuration file can run the tool in a completely automated way, outputting the XML file which is to be exported to the central data warehouse.

To configure the Adaptor, one needs to specify the SQL query that retrieves all the required data and exports this to one table. Such commands are grouped into scripts. Clearly some programming proficiency is necessary to understand and write such commands. Each BIRO partner uses his or her proprietary metadata model and the first step required is to develop a transformation/mapping to the BIRO data model. Next, a decision must be taken as to which BIRO indicators will be supported. Once this happens the mappings of the corresponding objects should be implemented.

For each BIRO partner providing diabetes data, several considerations must be taken into account when evaluating alternative approaches.
- The first step is to determine which data is needed for the construction of a local BIRO data warehouse and in which diabetes care systems this data resides. Useful data may be fragmented and distributed among various distinct databases.
- Experience has shown that these types of problems exist when queries draw data from heterogeneous databases (clinical, administrative, etc.).
- The BIRO local data warehouse approach assumes everyone wants to share and cooperate for BIRO local database integration. However, there must be an awareness of local diabetes centres that do not wish to integrate or share their data.

New BIROBox database interface

The old database connection required some programming proficiency and therefore, usability and clarity suffered because of this. The new updated BIROBox is much more user friendly as its use does not entail a knowledge of understanding writing script commands.

BIROBox v.1.0.3 downloads is available on BIRO Web site, software area. After the download is completed start the biro-setup_v1.0.3 wizard.

BIROBox installation wizard (Figure 3) is an executable installation, an effective and professional looking setup with several setup customization options such as BIROBox, Postgres 8.3, R 2.8.0, Miktex 2.7.0 Jva development kit and Java Crypto extension.

On the BIRO setup panel, choose the components to install option. Click Next.
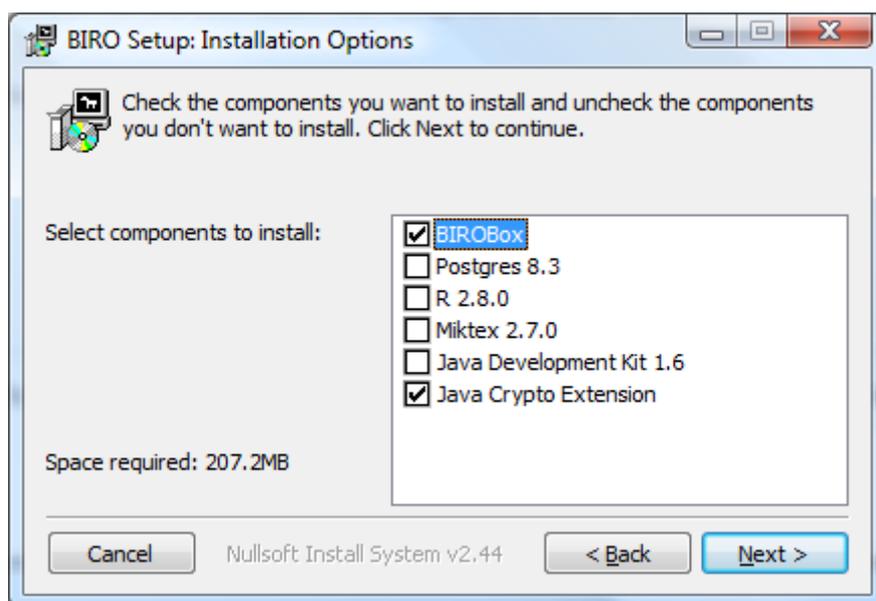
Figure 3: BIROBox installation, an attractive graphical user interface
with install wizard

To check that the installation has completed successfully, double click the runBIROBoxGUI.bat The main screen of the BIRO BOX GUI (figure 4) should appear .

SysAdmin problems with write-protected folders or files

This problem doesn't seem to have anything to do with BIRO software programming. The BIRO Box application working directory is in Program Files. After local installation of the BIRO Box GUI the potential users should be awared about an annoying thing of Vista write-protected folders!

To solve this problem we can do manually set write permission to the BIROBox application's folders. Navigate to the the directory or file that needs its permissions changed and we should be able to right click on the files/folders and change their ownership in the advanced security settings. Give full access to users, reboot and try again.

In figure 4 we illustrate how to set write permission for "C:\Program Files\BIRO\software_de_\output\xml"
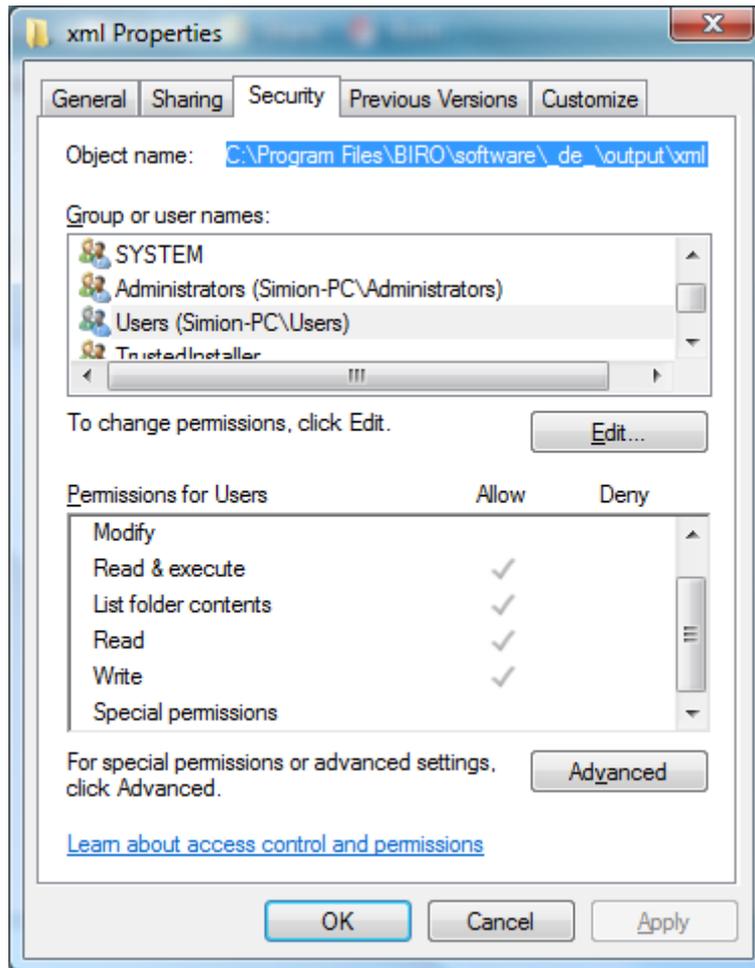
Figure 4: Set write permission to the BIRO Box application's folders

For Linux OS, to solve write permission you can do either: manually set write permission to the application's folder by use the "chmod" command to change the access mode of a file. A tutorial about the chmod comand can be found here:
 http://catcode.com/teachmod/chmod_cmd.html

Or set write permission when you use a GUI as is illustrated in figure 5.
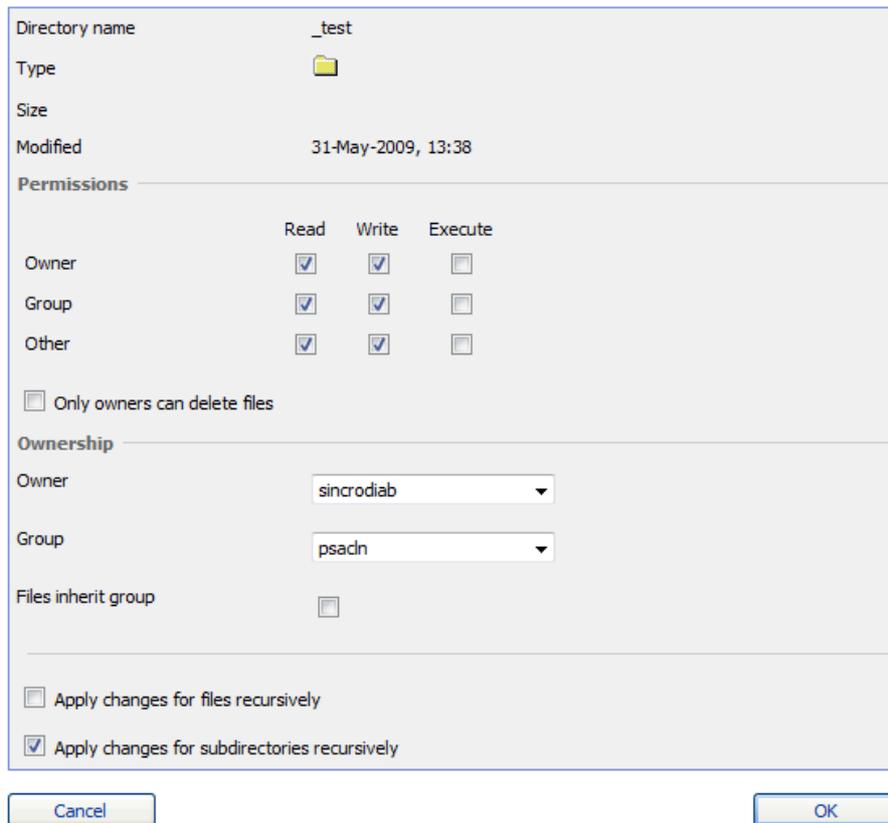
Figure 5: Changing a File or a Directory Properties

Mapping of the User's model to the BIRO model

The BIROBox has three major work areas in a graphical user interface with a few mouse clicks:

- BIRO Adaptor
- BIRO Database
- BIRO Communication software.
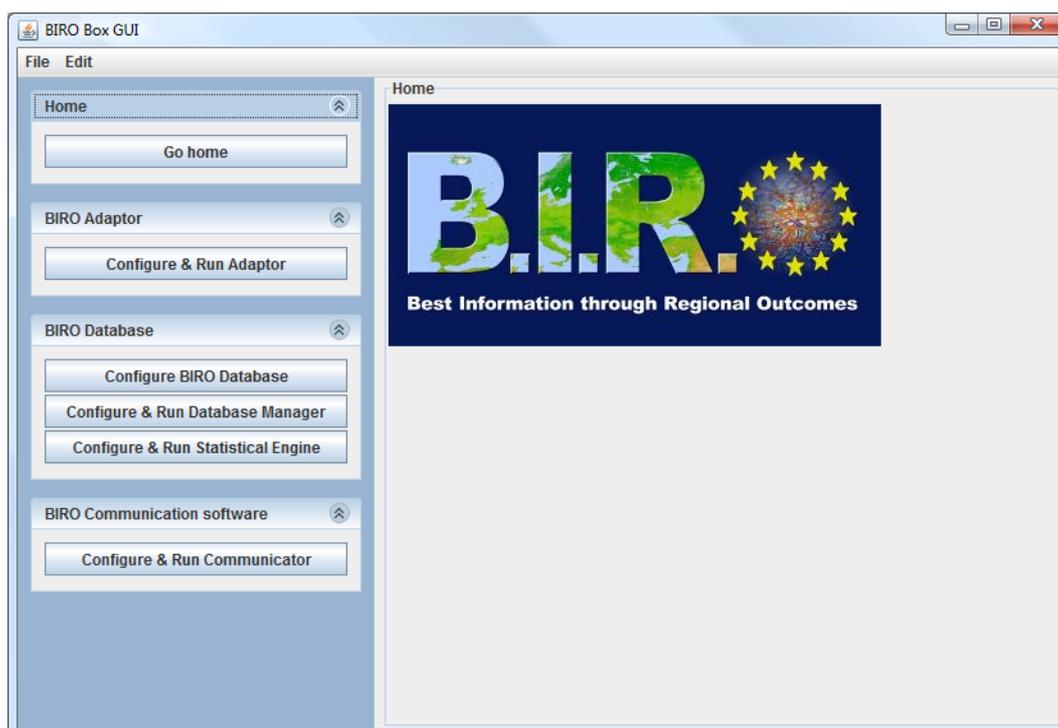
Figure 6: The main screen of the BIRO BOX GUI.

Each of the main screen work areas contains a number of individual functions that are serviced by the specific technologies that configure the BIRO database and configure and run the adaptor, the database manager, the statistical engine and the BIRO communicator.

Two steps are necessary for mapping of the user's model to the BIRO model:
- For static BIRO identifier fields. Many of these are designed to be unique within a region. They are non-temporal data, and therefore remain configured for the subsequent data extraction for BIRO data transfer.
- For field-mapping configuration. The BIROBOx allows configuration mapping between BIRO central database fields and local database fields.

Improved Key features for Data source configuration

As static BIRO identifier fields are non-temporal data, these remain configured for the next data extraction for BIRO data transfer. For configuration of other entities that handle various data source identifiers, each static field must be completed because these are all compulsory as they represent real world entities such as Clinical contact, Clinical contact email address, Country of origin, people, etc. They may all be assigned as identifiers (for handling various data source identifiers because many of these are designed to be unique within a region).

If a field is not filled or is badly configured the adaptor stops executing and reports an error indicating that this value format is incorrect (unrecognized).

During the evaluation of the BIROBox , we noted that filling the static fields may be confusing for the user. Therefore, in order to avoid a bad configuration (invalid data values such as

data source code, the country code 'xx', the geographical area code xxxxxx, etc.) some improvements were suggested for new BIROBox . These were necessary because the extraction from semi-structured information sources is mostly done manually and is therefore very time consuming (taking into account the immense amount of data). Such improvements have been made in the new BIROBox; these consist in real time help in the filling process.

For data mapping on temporal BIRO data fields on the BIROBox the process is clear, easy to use and provides much information. We have tested these fields through mapping configuration function on various types of data used in diabetes. We have performed GUI usability testing on databases: quantity which handles real numbers to various levels of precision and units (assuming there is an instrument available in real practice to generate the value e.g. Systolic blood-pressure: low: < 90 mmHg; normal: 90mmHg - 140mmHg; high: > 140 mmHg), identifier for handling IDs identifiers, count which handles integer values, Boolean for true/false (e.g. retinopathy=present), date for dates, time for times, date-time for dates and times, ordinal which handles text values which are associated with an integer, proportion which handles ratios and fractions. From an end user's perspective (e.g. medical users using visualization tools) and for a complete evaluation of this function of the tool, further tests are required based on different mapping scenarios on data recorded in the local legacy systems (potentially distributed across countries).

Problems during local application of BIRO Box GUI

Analyzing data involved in diabetes care shows that the local data exists in formats primarily intended for health care users and the BIROBox cannot easily and directly process every bit of data. Advanced data extraction and information integration techniques are required to process local data. Powerful tools for **E**xtracting, **T**ransforming and **L**oading (ETL) data from diabetes source systems into a local data warehouse are available today (tools such as Pentaho) and support data extraction from local users' applications in an efficient way.

There are therefore still some technical problems to be solved before the BIROBox can run efficiently. Such problems are inevitable and more will come to light as more partners start providing data. These should be solved by interactive collaboration between users and software developers.

A specific technical point was that data should be put into single MySQL (or another server table), before connecting to the BIROBox. The question of how this information can be extracted, transformed to a semantically useful structure, and integrated with an "ETL" process into BIROBox system has to be answered locally for each particular case.

Connecting to a BIRO MySQL Database

This section demonstrates how to set up a connection to a BIRO MySQL database from BIROBox. We must first ensure that the MySQL Database Server is running on our machine. The MySQL Server node in the PC Services indicates whether the MySQL Database Server is started.
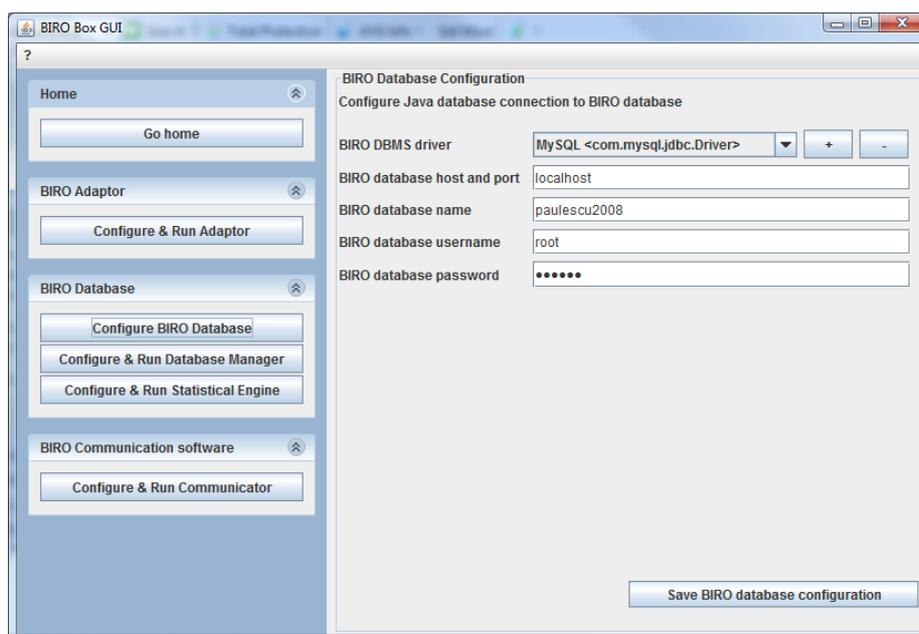
Figure 7: The MySQL Server Properties dialog box opens to configure BIRO MySQL Database

Once configured and sucessful connected to BIRO database, we can begin working with configure and run MySQL database manager in the BIROBox by creating new BIRO tables, populating tables with data, and running configure & run statistical engine based on SQL queries on database structures and content.

How to identify incentives for uptake and best use of BIRO?

Despite major weaknesses in attracting researchers to ICT in Medicine (weak public financial support for research), programs like BIRO offer strong stimuli for attractive research careers (such as PhD students with skills in the healthcare applicative sector of informatics). BIRO is based on high quality research and innovation in Europe and represents an excellent tool for public health research. Perugia University, the BIRO project coordinator, has been involving PhD students with skills in the healthcare applicative sector of informatics and therefore, is an example to be followed by Romania and other EU countries in this respect. This hypothesis has been verified in practice with the occasion of the recent National Congress of Diabetes (May 2009).

In our opinion, the following actions are required to increase incentives for the uptake and best use of BIRO:
- Increasing awareness among potential users of the existence of BIRO and its innovative ICT approach; the program should be better publicized, mainly through Web-based Services.
- Raising awareness about the potential of structured reports as provided by BIRO in the so called "business intelligence - BI" applications based on common dataset for metadata and common dataset for local data. An interesting example in this respect is the Google Analytics https://www.google.com/analytics/

- Improving public-private partnerships to understand and make use of the BIRO informatics tools for public health research based on Computer Science Technologies.

Data migration tools

The fundamental issue in technology transfer is the difficult problem of transferring data from different systems with different formats to one common central BIRO server. We have examined several possible solutions for migration, none of which seems perfect. We have studied the systems used in the three partner countries Malta, Cyprus and Romania for collection of the data that will be used in BIRO (including its format and size) for data analysis, data mining and BIRO evaluation.

Method of data base access

Available access types are dependent on the type of database we are connecting to. Thanks to ODBC (Open Database Connectivity), Java Database Connectivity (JDBC) and SQL, we can connect to various databases and manipulate data in a standard way.

ODBC, a C-based interface to SQL-based database engines, provides a consistent interface for communicating with a database and for accessing database metadata (information about the database system vendor, how the data is stored, and so on). Individual vendors provide specific drivers or "bridges" to their particular database management system.

Java Database Connectivity (JDBC) is an API for the Java programming language that defines how a client may access a database. It provides methods for querying and updating data in a database. JDBC is oriented towards relational databases.

In practice there is a JDBC driver available for every database, and if not one can still use ODBC connectivity.

The BIROBox can work with many different database programs including:
- PostgreSQL
- MySQL
- MSSQL, etc

The new version of BIRO Adaptor has added an important function: input data from a CSV (coma separated value) file.

Pentaho Data Integration

After much time and effort in testing various technologies (free software) we found the most viable technology option, an open source software called **Pentaho.** This open source software seems to be the "world's most popular open source business intelligence (BI) suite and is probably the best free option available today for extraction and consolidation of data from disparate sources using Data Transformation Services" http://www.pentaho.com. We have tested Pentaho Data Integration version 3.0 and then version3.1.

Pentaho Data Integration (PDI, also called Kettle) is the component of Pentaho responsible for the **E**xtract, **T**ransform and **L**oad (ETL) processes. Kettle is part of The Pentaho BI Project, a tool that extracts data and transforms it into a dimensional data model for analysis.

Different Privacy legislation (WP5)

As a result of the Privacy Impact Assessment Work Package (WP5), many privacy measures have been adopted in order to ensure secure data transfer: aggregation by group of patients, date fields approximated to time interval (e.g. months), use of pseudonyms for service centers, password access for local administrator and prompting by client programs to send encrypted bundles to the BIRO central server.

The security of medical data is one of the most sensitive topics to consider in data transfer; each potentially vulnerable point must be detected and steps taken to prevent intrusion. According to the EU Data Protection Directive, cross border flows of data are allowed only when an adequate level of privacy protection is envisaged in countries involved in the operations. We have come up with the following considerations to ensure a secure environment during data transfer:

- The application server for the Import portal must not serve patient data. The Import portal is meant to bring data in, therefore it will have no "read" capabilities for its users.
- The web and application server will reside on a different computer from the actual database. The postgreSQL database server will be setup to accept incoming data from only the web and application server's ip. The web and application server will not have read permissions on tables that it only needs to write to. These steps ensure that no data will be tampered with during transfer from the web and application server. Similar steps should be taken for any other applications that might connect to the centralized data source.
- The database and the application servers will have OS level firewalls that only open ports needed by the applications, generally 80 for web content, 443 and 8443 for secure encrypted web services & applications, and 5432 for postgreSQL.
- The postgreSQL and Web Application port communications will be encrypted using SSL, thus ensuring that any data being transferred is unreadable.
- Both the Web Application and the operating system applications will use a strong password policy standard.
- It is assumed that the institutions contributing data to the centralized database are online under a static ip, or at least a more distinct ip range. Adding a new user for the Import Portal will imply that the ip or ip ranges are also specified, giving the Import Portal the capability of refusing users if they are not connecting from where they should be.
- A monitoring tool could optionally be built to allow ongoing monitoring of all security layers: firewall level, application level and database level.
- No patient demographic information will be kept. Patients will be referred to with their unique ID from the incoming database.

Connection to EU information systems (Web Portal, WP 11)

At the BIRO Central Server there is an application called the SEDIS (Shared European Diabetes Information System) that will receive and analyze data and produce a number of reports in HTML, Excel or pdf format.

XML schema produced in WP3/WP4

An XML Schema is a specific XML language that describes how BIRO data is organised, datatypes of BIRO data, the structure and the types of an XML data source.

In general, hospital information systems are operated independently of each other. With XML schema the BIRO project specifies how XML the data will be organsied and the datatypes of the data integrated for global statistical analysis. one can express all data constraints (datatype of the data, the data's range of values, how the data is related to another piece of the data - data items that can be calculated based on other data items, etc.) described in WP3/WP4 using XML Schemas. In keeping with the project's technical description, partners agreed to structure their XML documents in conformance with an BIRO XML schema.

As most of the details have been given in D4.2: XML METADATA DICTIONARY, what follows is a short description of all procedures that each BIRO partner/user should follow in order to utilize the BIRO XML schema. This section describes the BIRO XML schema principles and is only meant to be used as a guideline.

For the integration of data from diabetes centers with the BIRO statistical metadata, the partners/users need to export the local registry databases to an XML file. The XML Schema of the BIRO export file is given in the WP4 description, file name BIRODataSet.xsd with an example in the WP6 section. These data items can then be defined individually based on the BIRO requirement (WP2: the data items required to fulfill the requirements of the core indicator list).

Partners have to decide which tables and columns or CVS files from their relational databases are to be included in the XML documents.

A clinical local BIRO data repository has to be created to enable the sharing of medical information among health and medical institutions (which can be used to support the process of Disease Management locally) and to enable submission of variables (specific BIRO metadata transmission) whose values are defined by a controlled common vocabulary provided by WP3.

An XML schema was designed using indicator data from WP2 and WP4 through which an effective clinical document was generated from the BIRO local repository. The data elements were structured into the following themes:
- The profile of the clinical site providing the patient data extract
- Data regarding clinic demography
- Metadata regarding the BIRO data items from the specified data source
- Data items that can be calculated based on other data items

The schema BIRO Data Set was analyzed according to the BIRO indicators reference information model. This schema details the BIRO data fields identified in Work Package 3, alongside their unique identifiers. One needs to create the root element within which the XML representation of the data is nested.

For our example, we'll create a root element called < BIRO Dataset> to hold the other elements we will create:

<BIRO Dataset>
...other elements go here
</BIRO Dataset>

An example of how data is stored in the schema is shown below:
<xsd:simpleType name="BIRO Dataset">
<xsd:restriction base="xsd:string">
<xsd:enumeration value="PAT_ID" id="BIRO001"/>
<xsd:enumeration value="DS_ID" id="BIRO002"/>
<xsd:enumeration value="TYPE_DM" id="BIRO003"/>
.
.
.
.
<xsd:enumeration value="SELF_MON" id="BIRO044"/>
<xsd:enumeration value="EDUCATION" id="BIRO045"/>
</xsd:restriction>
</xsd:simpleType>

It is also possible that one may want to add some information to the XML document that isn't part of one's relational database. As new parameters are added to BIRODataSet.xsd over time, these will simply be added on and immediately become available for use in the schema example listed above.

This information might be used to indicate routing or behavioral information. For example, we might want to add a source attribute (the profile of the clinical site providing the patient data extract), so that the BIRO partner can decide which data source handler needs to be run to parse the document being passed. If we choose to add information about the document like this, it makes the most sense to add it as attributes of the root element we create.

For the test purposes of our example (Diabcare dataset), in Bucharest we assumed that all the information in our structure was relevant to the BIRO data integration process.

Scalability and extensibility of the BIRO product to Malta, Cyprus and Romania

Taking into account the limited number of patients used for the BIRO technology tests done so far, it is too early to do this evaluation because:

- Scalable implies that we can easily increase, or "scale up", our BIRO system as traffic increases and, allows customers to analyze their data exactly as before but faster, at lower cost and with a better quality of results. The BIRO architecture is open and modular, and built as scalable modules that distribute the load across multiple BIRO local servers, hence, capable of scaling to tens and hundreds of terabytes of data and thousands of queries per seconds.
- Extensibility (maintainable) implies that it is possible to simply modify one part of the system - changing over from one database to another, for example - without affecting other areas.

Additional specific tools for technology transfer

Applications that read in the local registry of data should be able to back translate the diabetes data they receive into their models in order to display or manipulate the results for the storage and mappings of data components required for BIRO.

BIRO Preparation of the Data

In this step of the BIRO technology transfer development the data that will be analyzed by the data integration tools prepared in Deliverable No.6 is chosen., Data from different sources can also be integrated integrated.

New data tables are formed that meet specific requirements of the given Data Dictionary set and integration tools. Preparation of the data may involve cleaning the data, assigning classes to the data examples (data existing already and presented above). During this step, data cleaning, data quality checks and data integration are performed. This means that individual columns are checked for valid data (e.g. ranges for numeric values).

The cleaned data can be further processed by feature selection and extraction algorithms (for example SQL scripts). There should also be a policy established for error handling. Our preliminary tests (Jasper reports) show that missing values are not adequately dealt with. In the case of categorical variables, a category defined as "missing" and labeled accordingly by the data provider is treated as any other category.

Usage and availability of open source software

Since most of the details have been already been given in (WP6: BIRO adaptor, WP9: COMMUNICATION SOFTWARE), the current document is only meant to be used as a guideline.

To implement BIRO software, we need the following software and resources:
- Java Developer Kit (JDK) version 6 or version 5
- Java EE-compliant web or application server
- Tomcat web server 6.0 and/or GlassFish application server v2
- SOAP-based technologies for deploying services on the internet, due to its ability to transmit data directly over HTTP.
- An easy-to-use BIRO adaptor graphical user interface (GUI).

- A business intelligent (BI) solution for data transformation/integration

Configuring the Java Runtime Engine or JDK

Several modules in BIRO have been written using industry-standard Java (WP6: BIRO adaptor, WP9: COMMUNICATION SOFTWARE), and therefore require either Java runtime or Java compiler components and Tomcat servlet engine to be installed on user's computer.

This is a short description of all the procedures that each BIRO partner/user should follow to configure the Java Runtime Engine or JDK in order to utilize any of the Java cases discussed in WP6 and WP9.

These Java components, the Java Runtime Environment (JRE) and the Java Development Kit (JDK), are available from Sun Microsystems and are installed separately from BIRO system.

http://java.sun.com/j2se/1.4.2/download.html
Sun 1.4.2 JRE and JDK (J2SE 1.4.2)
To view or change environment variables (for example, Windows XP Setup):
1. Right-click My Computer and then click Properties.
2. Click the Advanced tab.
3. Click Environment variables.
4. Click one the following options, for either a user or a system variable:
   - Click New to add a new variable name and value.
   - Click an existing variable, and then click Edit to change its name or value.
   - Click an existing variable, and then click Delete to remove it.

In order to be able to work with Java, one needs to have:
   - Copies of Sun's Java Development Kit,
   - Apache's httpd Web server and mod_jserv module, and
   - The Tomcat servlet engine, and configure them so that they're all working together.

To double-check that the Java SDK is installed correctly on the computer, open a command prompt (i.e. the Command Prompt or MS-DOS Command Prompt in Windows, or Putty under Linux). Try the two commands shown below. If you get similar output, the system is properly installed. If your operating system doesn't recognize the commands, you may need to reboot for changes to your environment variables to be detected.

> *C:\> java –version*
> *java version "1.6.0_01-ea"*
> *Java(TM) SE Runtime Environnent (build 1.6.0_01-ea-b01)*
> *Java HotSpot(TM) Client VM (build 1.6.0_01-ea-b01, mixed mode)*
>
> *C:\> javac*
> *Usage: javac <options> <source files>*

> *where possible options include:*
> *...list of options...*

It is important to note here that Java code is not read line-by-line, as with PHP; it is first converted into a servlet (a byte code version of the program) and then invoked by a servlet engine (such as Tomcat) to perform the required actions. Once the servlet is executed, the results are sent back to the client. Since the servlet engine has to compile the servlet the first time around, displaying a Java page can take a little when the user accesses it for the first time; however, the next time around, response time will be dramatically reduced, since the servlet will have already been compiled and therefore be ready for immediate use.

Compliance of BIRO specification with policy programs

Different categories of users or consumers (national users) will have access to the aggregated data/metadata stored in the BIRO central server. Access will be gained through various reporting tools and applications. This will enable participants to provide a set of indicators according to BIRO Work Package 2 (a list of Core Indicator Candidates based on the published scientific literature) that is relevant for practice, policy and research.
Gathering diabetes data (data integration, data storage and data usage) was very time consuming in the past, but with BIRO's modern technology and open source application existing today, it is much easier to collect data from various sources. For example, Pentaho is an Open Source ETL tool which gives the user a standard set of functions, database connections and error handling rules that help the BIRO local users analyze data errors and filter them.

The BIRO results will provide policy makers and management with increased information about centres of excellence at Regional/National/European level. Knowing who the BIRO users are and understanding their needs is the essential foundation for effective implementation of this project. The varying needs of a diverse and large number of users of statistical metadata highlights the strategic nature of the BIRO project.

BIRO is a statistical metadata system. Therefore, at national level the system could form an integral part of the strategic direction of a health care organization. In the latter case it is vital that health care national management (e.g. Ministry of Health) be directly involved in the BIRO metadata project for an extensive implementation of the system. For those office managers involved in studies and reports with remote harmonization of metadata or remote integration of data sources, this BIRO technology transfer report should constitute valuable reading.

The fundamental precondition for the efficient, cost-effective, quality data sharing used by the BIRO Technology is the training of users to acquire a greater and deeper knowledge in the field of the diabetes indicators and BIRO information technologies. Potential BIRO users should:

- Initiate a focused program to educate and train user epidemiologists, statisticians, scientists, diabetologists and engineering professionals to disseminate and implement the BIRO system extensively.

- Develop training materials and coordinate planning efforts to implement the BIRO technology in short-term.

Choose the Data to Include

Because the BIRO technology is based on databases connecting various partners, users need to have a direct link with a local diabetes dataset.

The BIRO system is based on the philosophy that a user does need expert knowledge to specify a query and does have to know how exactly a query is answered. This category of 'expert users' would want control, or at least information, on data sources and data transformations (mappings) used in the process, most importantly for data quality assessment and integration purposes.

SECTION 3. Technology Transfer: Dissemination And Training Activities

This section discusses briefly the BIRO technology dissemination and training in Cyprus, Malta, and Romania under the following headings:
- Benefits for End Users on the National Level
- BIRO Information Meeting in Cyprus, Malta and Romania
- Training Session in Cyprus, Malta and Romania
- Discussion
- Conclusion

BIRO End Users

Potential BIRO users include:
- diabetes care units, primary care units, governmental institutions, political decision makers, public officials, academia, researchers, archives, librarians, journalists and the general public.
- International organizations e.g. EASD (European Association for Study of Diabetes), IDF (International Diabetes Federation), DG-SANCO (the Directorate General for Health and Consumer Affairs), European Union (Commission and Parliament), WHO/ Europe.

Feedback on the use of BIRO can be provided by clinicians, diabetic associations, policy makers, governmental institutions etc). BIRO users need to be provided with the maximum information about statistical outputs that can be obtained via the BIRO statistical portal website. Consideration of appropriate risk mitigation actions is a significant part of the BIRO project governance.

This subsection explores some of the potential barriers to the adoption of BIRO metadata solutions - technical, organizational and human - that were identified by various users discussions conducted as part of the Del 12 research.
The human factor is fundamental to the successful adoption of BIRO metadata system. Therefore users need to be provided with:

- Documentation for understanding and using data
- Documentation for finding and retrieving data
- BIRO data integration steps
- BIRO data integration screenshots and tutorials
- BIRO data integration case studies
- BIRO data integration articles

Benefits for End Users at the National Level

BIRO will support handling access of users to local microdata to help the evidenced-based approach to DG-SANCO Public health policy development with respect to cross-border data

integration. BIRO will also help local users to better discover, understand, interpret and interrogate needed data.

Access to aggregated patient data will allow clinicians to monitor treatment correlations and trends and therefore provide more informed patient management decisions.

Brief of BIRO Information Meeting in Cyprus, Malta and Romania

The BIRO technology potential users were generally interested in the philosophy and functioning of the system, and some of the users have requested future versions for further testing. The BIRO technology presented during the recent Romanian Congress on Diabetes (May 2009) has attracted much interest, mainly among young diabetologists who are interested for data analysis in the perspective of the PhD thesis. The chairman of the Congress's session where the BIRO technology was presented considers that this technology should be disseminated at the national level in Romania through workshops specially dedicated for the training in BIRO Technology Transfer. It was mentioned that the BIRO technology is a necessity for all diabetes centers in the country due to a lack of such technology and due to lack of training in data analysis (even in using the dedicated proprietary technology, for example, SPSS).

Brief of BIRO Training Session in Cyprus, Malta and Romania

BIRO technology transfer client

Most users require instructions on how to operate the Client; these can be found in the BIRO User Guide (BIRO adaptor, how to access the BIRO Data Server, Database Engine, Central Engine, Statistical Engine, Communication Software.

BIRO technology transfer use

The later version of the BIRO Box software support the production of printed PDF and HTML reports, and produce analysis tables. Results are fed back to local regions in a benchmarking exercise, to inform local care providers about their services, and for policy makers to assist local quality development. BIRO Technology offers an opportunity to inform the prioritisation of the choice of clinical performance and quality indicators. Our BIRO Technology test has the advantage of being real data that reflects existing clinical practice and inherent to these is the feasibility of collecting such process and outcome indicators.

We believe that, through training and dissemination, BIRO technology components will have regional, national and European service dimension for diabetes care and prevention. The BIRO infrastructure will contribute to EU diabetes care and prevention by optimising access and exploitation of already collected data.

BIRO Report Contents

Chapter 1: Demographic characteristics
      1.1. Age (Classes)

Chapter 2: Clinical characteristics
      2.1 Diabetes Status
      2.1.1. Type of diabetes
      2.2 Risk Factors
      2.3. Diabetes complications

Chapter 3: Health System
      3.1. Structure (provider level)
      3.1.2 Average diabetes population per center
      3.2. Structural quality
      3.2.1 Hospital beds per 100,000 population
      3.2.2 Physicians employed per 100,000 population
      3.3. Processes (individual level)
      3.3.1. Foot examination
      3.3.2. Eye examination
      3.3.3 Measurements examination
      3.3.4 Treatment
      3.3.5 Management
      3.3.5.2 Visit Frequency

Chapter 4: Population
      4.1.1 Total Population
      4.1.2 Life expectancy
      4.1.3 Mortality Data

Chapter 5: Risk Adjusted Indicators
      5.1. Epidemiology
      5.1.1 Prevalence of diabetes mellitus per 1,000
      5.2. Process Quality
      5.3. Outcome quality - intermediate outcomes
      5.4. Outcome quality - terminal outcomes

SECTION 4. Illustrative Data Report

The data resources avalaibility (connect to medical data) is at the heart of the BIRO project for diabetes and health benefits. The data and results in this chapter are illustrative of the data contained in the smal sample database. Further cohorts will be added to this collection, and over time the significance of the regional variations will become more pronounced. However, there is currently enough sample of data to ilustrate how the BIROBox produces some meaningful analysis.

1.1. Age (Classes)

Reference Date: 30/06/2008

Age Classes	Female (%)	Male (%)	PT	
0 - 34	8 (61.54)	5 (38.46)	13	13
35 - 54	44 (57.14)	33 (42.86)	77	77
55 - 74	93 (52.54)	84 (47.46)	177	177
75 +	10 (62.5)	6 (37.5)	16	16
	155	128		283

Age Classes (by Gender)
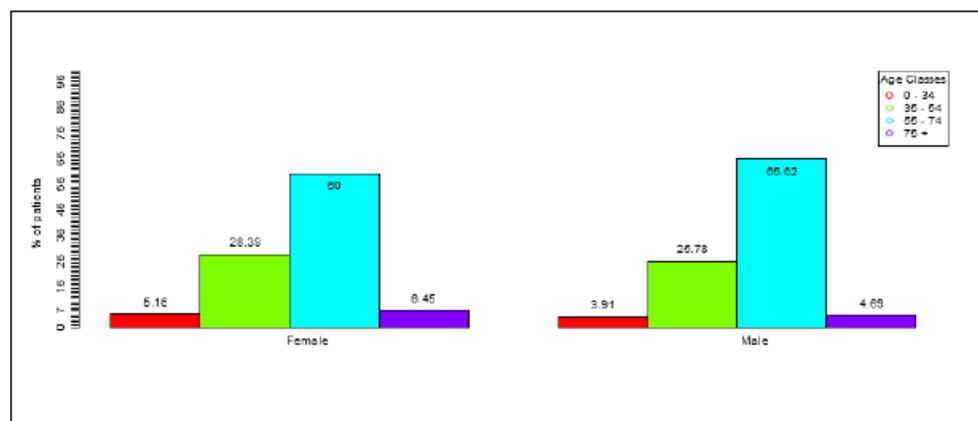
Barplot: Age Classes (by Gender)

Age/sex distributions

Discussion

Computer applications can be of great scientific importance, particularly in diabetes, as data collected can be analyzed and this can provide an insight into the quality of health care, thus allowing improvement in care to be made. This technology transfer activity made it possible to delineate practical problems encountered during the installation and use of BIRO software.

The provision of reliable and comparable data needs to take into account various difficulties. There is a general lack of interoperability across different data formats and architectures; also, different naming conventions in diabetes result in heterogeneous data at the European level. Bringing together data with different patterns, structures and syntax, and allowing users to access information located in different places can be a challenge. In this respect, the BIRO system sets the basis for a new form of collaboration.

Various tools must be available to implement the solution and allow users to interact on the whole cycle, from the collection of the individual parameters to the interpretation of diabetes indicators. More training is required to fully exploit the potential information yield of medical records. Technology transfer in BIRO was the key to adapting the system for the immediate needs of its users. This process must be repeated and refined in order to allow a wider implementation of the system.

Practical decisions have been derived for the initial release of the software. All visits from a zero would be filtered for upload each time the upload is undertaken, and the upload is planned to be made every 6 months. For instance all visits from the beginning of the year, say January 2007, would be filtered for upload in the file of June 07, Dec 07, Jun 08 and Dec 08 etc for the whole cycle, until a new zero date is agreed.

Once the data/view is created one can save the filtered records as a CSV file. One can always tweak the data after in Excel and save as a CSV file through it. The file may also be modified by the respective partners, directly to replace and remove patient ID, without undermining the integrity of the data and respecting confidentiality. Each upload will be overwriting the previous. However, a copy for backup purposes may always be taken.

The following potential barriers to the local adaptation of BIRO have been identified:
- Clinicians may have little awareness of EU standards in data classification
- Local software may not comply with BIRO and/or produce exports
- Communication may be lacking between policy makers and researchers
- Systems implemented may not be properly evaluated
- Software products may not be interoperable
- Financial support for improved data quality may be scarce
- Multidisciplinary training across Medical/IT disciplines may not be encouraged
- Procedures to ensure privacy, confidentiality and security may be lacking

BIRO offers strong stimuli for an attractive research and training, with its emphasis on high quality research and innovation.

Possible incentives for its uptake include:

- Showcases and pilots to demonstrate BIRO innovation, using means e.g. web services for public involvement
- Raising awareness about the power of structured Reports as "intelligence services" for the organization of modern health systems
- Public-private partnerships to understand and implement efficient BIRO IT solutions
- Presentation of examples of usage of BIRO as the best practice for the evaluation and better planning of diabetes care.

Conclusions

1. The BIRO project provides policy makers and managerial levels with a platform for the use of diabetes information at Regional/ National/European level

2. Learning from direct users and understanding their needs is the essential foundation for an effective use of a system addressing a diverse and broad audience

3. Technology transfer has successfully presented a new stream of open source tools developed by the BIRO collaboration, showing: (i) increased opportunities for innovation, quickly integrated into flexible tools; (ii) a range of practical problems, that can be rapidly solved on site through test rounds; and (iii) a number of technological problems that must be addressed separately and solved through the support of a community of programmers.

4. The fundamental precondition for the efficient and cost effective data sharing proposed by BIRO is the continuous training in the field of diabetes information.

5. The BIRO project confirms that practical applications in health care, as in any real situation, to be successful and reliable, must pass a range of serious tests of feasibility, to be repeatedly carried out at any stage of their implementation.

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