Data Sources and Information to be Collected for a Romanian Diabetes Register

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Abstract

Diabetes is a serious condition that damages many systems and organs, mainly the blood vessels and the nerves. The importance of the diabetes and its complications, along with the prevalence of the disease makes it a major public health problem worldwide. The spread of diabetes and its complications can be evaluated, and action steps based on this information can be taken, by the use of national diabetes registers and databases. A register of a chronic disease (such as diabetes) is an application used to capture, manage and offer information about chronic diseases to support an organized management of patient health care. Till now in Romania there are there are only disparate initiatives at hospital level, without any systematized regional or national monitoring through registers. The aim of this paper was to identify a way to help in the developing a national register for diabetes, that makes use of current medical information sources, and to develop the structure of a diabetes register and database for diabetes in Romania. The paper presents the medical sources of information that can provide data to a diabetes register, their degree of trust, algorithms for entering new diabetes cases, or removing cases from the register. The structure of a diabetes database, and registry, and for a form to input data in them is detailed in the article.

Keywords: Diabetes; Register; Medical data sources.

Introduction

Diabetes mellitus is a chronic disease that manifests through hyperglycemia, due to insufficient insulin secretion by the pancreas, ineffective use of the insulin by the organism, or both.

Diabetes is a serious condition that damages many systems and organs, mainly the blood vessels and the nerves. In time it leads to complications like: micro and macro angiopathy, retinopathy (a main cause of blindness, and visual disability), neuropathy, heart disease, kidney failure, and diabetic foot disease. These complications affect the physical and psychological well being of those affected. It finally leads to disability and premature death. Diabetes comes with high costs for the sufferers, for the health care systems, and for the economy through disability and a shorter life span [1].

The importance of the diabetes and its complications, along with the prevalence of the disease makes it a major public health problem worldwide. The prevalence of diabetes is rising on the globe every year [1].

The frequency of the diabetes, and the number and severity of its complications can be lowered by careful and early health care measures.

The spread of diabetes and its complications can be evaluated, and action steps based on this information can be taken, by the use of national diabetes registers and databases. A better survey of chronic disease incidence, at country level, through control and prophylactic programs increase the odds of improving the health of their citizens [2].

A register of a chronic disease (such as diabetes) is an application used to capture, manage and offer information about chronic diseases to support an organized management of patient health care [3].

In the case of diabetes such kind of registers can be used for the following:

- At physician Level: to generate reports for physicians that show the quality of diabetes control based on the level of glycosylated hemoglobin (HbA1c), to offer information about deviations of the care from what guidelines are saying, to identify patients that have prescriptions outside therapeutic limitations, to create reminders about patient diabetes health care management, to identify future pending activities, to generate reminders to be sent to patients when diabetes health care tasks are getting close to the appointments dates, to create lists of high risk patients that need more intensive health care management.

- At organizational or higher level (regional or national): registers can provide statistics in real time about the disease, can offer clues about aspects that are not well dealt about, can offer information based on which health care policies can be modified to improve patients' quality of life (e.g. modifying the price of compensated drugs, based on disease burden, social, health, human and economic impact, can offer information to help the implementation of national strategies for prevention, or for modifying existing strategies, can provide data to study possible risk factors linked to the disease of interest.

The estimated percentage of deaths of all deaths, attributable to diabetes for all ages, in the year 2000, in Europe was 6.6% for males and 5.1% for females [4]. At global level the percentage was 5.2%, and the global excess mortality attributable to diabetes was estimated at 2.9 million deaths.

Another estimation of proportional mortality in the World Health Organization, European Region in 2004, found that from all deaths 43.8% were due to circulatory diseases, 21.3% were due to cancers, 1.3% were due to diabetes, 4.7% were due to respiratory diseases, 10.2% were due to other non communicable diseases in males, and 57.0% were due to circulatory diseases, 17.9% were due to cancers, 2% were due to diabetes, 3.2% were due to respiratory diseases, 10.4% were due to other non communicable diseases in females [5].

The prevalence of diabetes for all age-groups worldwide was estimated at 2.8% in 2000, and 4.4 in 2030. The total number of people that have diabetes was 171 millions in 2000, and is projected to rise to 366 millions in 2030 [6].

In Romania the prevalence of diagnosed diabetes in the general population, for all ages, per 1000 individuals was 40, in 2005. Also the standardized annual incidence rate of diabetes per 100000 populations 0-14 years was 17 in 2005 [7].

Till now, in Romania there are no national registers to monitor non transmissible chronic diseases, except a first version of a National Cancer Register (CanReg 4) – developed by IARC (International Agency for the Research of Cancer)[8]. This application allows only manual input of data, verification, validation, and a few set of analyses. Manual input of cases, based on multiple medical documents, has a high level of subjectivism, generates recording errors, is difficult and requires an important body of qualified personell that has to process a huge volume of documents, to summarize, and abstractize the cases. Between 2004-2005, in the Phare EU project: "Improving the Capacity of Monitoring and Evaluation of Health Status in the Framework of the Health Care Reform", component two: Cancer registers, there were defined the technic-functional specifications of the Registrator manual, can be used in a Cancer register [9].

For other chronic diseases, other than cancer, there are only disparate initiatives at hospital level, without any systematized regional or national monitoring through registers. This deficiency of

recording and monitoring is underlined in the Institute of Public Health Bucharest report: "Description on the National Informational Health System in Romania" - 2003 [10].

The aim of this paper was to identify a way to help in the developing a national register for diabetes, that makes use of current medical information sources, and to develop the structure of a diabetes register and database for diabetes in Romania.

Material and Method

In order to identify the current situation of medical information sources that can provide data for a register of diabetes in Romania several semi-structured interviews were undertaken with key personell in several hospitals in Cluj-Napoca, interviews at the Diabetes Institute of Cluj-Napoca, interviews with pharmacists, and with laboratory personell. For the same aim a literature review of the current situation of the medical information system regarding diabetes information was undertaken.

Next we developed the structure of a form to enter data about new diabetes cases, to be used in hospitals. The structure is identical with the structure of a database of records at a regional and national level. From this database information will be retrieved to be stored in the national register for diabetes. The structure of the database for the register of diabetes was created. For several other sources of information the useful fields of information for the register of diabetes were identified. For each medical source of information the ease to retrieve data in Microsoft Excel file format was studied, and the degree of trust for the data quality was qualitatively assessed. Several algorithms were developed to identify when and how a new case of diabetes will be entered in the register of diabetes, and when a case will be removed from the register.

Results

Data Sources for a Diabetes Register

Interviews with key personell in the health care system in Cluj, helped to identify medical data sources of information that can be used for a Romanian national diabetes registers. The medical information sources identified were: institutional diabetes databases, institutional medical records databases, Diagnosis Related Groups information system, pharmacy data sources, laboratory data sources, and the death statistical bulletin data source.

Institutional diabetes databases

Some hospitals, or medical institutions (usually diabetes medical institutes, or diabetes wards in some hospitals) have chosen to adopt diabetes databases. These kinds of databases are not requested in the Romanian Health Care System. Each institution that uses this kind of databases has its own set of items stored about diabetes.

Data from these databases can be retrieved more or less difficult, in a suitable format (an .xls file type), and then can be imported in the diabetes register. Some medical entities use closed source software that doesn't have software maintenance, and the retrieval of the data inside their databases may prove to be difficult or impossible. Because the data in these databases was collected specifically for diabetes cases, these resources represent an important and reliable source of information for a national diabetes register.

Institutional medical records databases

Some hospitals make use of applications to maintain medical records databases. These databases usually store data about diagnosis (primary and secondary diagnosis), medical history, therapy, laboratory tests, epycrisis, and recommendations on patient exit from the hospital. This databases can be used to identify cases of diabetes and other useful diabetes information.

Data from these databases can be retrieved more or less difficult, in a suitable format (an .xls file type), and then can be imported in the diabetes register. Some medical entities use closed source software that doesn't have software maintenance, and the retrieval of the data inside their databases

may prove to be difficult or impossible. Some applications are used by many hospitals. This can make the export of information for diabetes register more easily because all hospitals that are using it, have the same format for the database. Equally the export can be more difficult if the application is not flexible enough to allow the export, or there are no maintainers to allow for this export operation. Some of these applications allows exports for Diagnosis Related Groups (see below), and also may have laboratory databases inside (see below).

Diagnosis Related Groups (DRG)

Romania Health Care System makes use of Diagnosis Related Groups (DRG) system in hospitals. DRG is a system to classify patients based on diagnosis, interventions, and other clinical data. Also this system allows for assessments of the relationship between the cases that are treated in hospitals and their costs [11]. Now the AR-DRG v.5. [12,13] Australian version is in use in Romania [14].

For this data source type, an .xls file can be exported with ease, because the data for DRGs is stored in Microsoft Access databases.

Data that is useful for the diabetes register is represented by: the last and the first name of the patient, the personal numerical code (CNP), the diabetes type – for patients where diabetes is the primary diseases and also for patients where diabetes is an associated diseases.

Pharmacy data sources

This data source is represented by a modified export of pharmacies compulsory reports for the Social Security House (CAS). All pharmacies in Romania have to record data about all their issued receipts. Different programs are allowed to be used to maintain this database. Each pharmacy has the right to purchase and use any program for this, provided it can export specific data for the CAS.

The export that each pharmacy has to send to CAS is an .xls type file. This file contains many fields. Only a few fields can be used to update the information in the diabetes register (Numerical personal code, disease code, drug used).

Laboratory data sources

The Romanian Health Care Systems allows for public and private Laboratories to function. It is up to these laboratories to implement or not any database for their tests. Where these databases exist, information can be filtered and exported to be used in the diabetes register. Important data for the register is represented by metabolic control tests, like: glycemia, glycosuria, and glycosylated hemoglobin, and also: cholesterol (HDL, LDL), triglycerides, creatinine, urea, uric acid and the proteins in urine.

Data from these databases can be retrieved more or less difficult, in a suitable format (an .xls file type), and then can be imported in the diabetes register. Some medical entities use closed source software that doesn't have software maintenance, and the retrieval of the data inside their databases may prove to be difficult or impossible.

Death statistical bulletin data source

The main source of information about deaths, and death causes, in Romania is represented by the Death statistical bulletin. This is a document completed and stored at Civil Status Offices [15]. Civil Status Offices are Town Hall offices. The Death statistical bulletin is completed based on medical certificated of death ascertainment written by a physician that that ascertained the death [16]. The data in this bulletin is then processed, by the Central Statistical Direction. Useful data can be retrieved for the diabetes register, because this document stores information about the cause of death (direct cause, previews causes, and initial morbid status), other important morbid data.

The structure of a national diabetes database, national diabetes register, and of a new diabetes case report form

In the following lines the structure of a national diabetes database, national diabetes register, and of a new diabetes case report form (named the DIA form) is presented. The data is grouped in sections. For each item of information, the form's visual input element type is presented (e.g. combo box, text field, …), data type and length for the information to be stored in the database. All these items will be used for the new diabetes case report form, and also for the national diabetes database. The items marked with * will be used for the national diabetes register.

The structure of the diabetes database, register and new case report form are presented in Table 1.

Details on the algorithms for entering and removing cases of diabetes, or diabetes information in the diabetes register

<u>Algorithm D.1. For register data entry from source files</u>

If the source is the form DIA, or institutional records, the information from these sources can be entered in the diabetes register, using the following cross-checks:

1. If the register has data about a patient and a new DIA form is submitted (source 1) or a new registration in the institutional records is submitted (source 2) for that patient, information relating to these recordings will be overwritten in the registry on the corresponding positions .

Table 1. The structure of a diabetes database, diabetes register, and new case report form

Item	Form element	Data type
<u>*Health care provider data:*</u>		
County	combo box according to SIRUTA's # county codes	number (unsigned integer), 2 bytes *
City	combo box according to SIRUTA's city codes	number (unsigned integer), 6 bytes *
Hospital code	text field	text, 6 characters
Ward	text field	text, maximum 30 characters
Ward code	text field	text, 5 characters
<u>*Data about the patient:*</u>		
First name	text field	text, 40 characters *
Last name	text field	text, 40 characters *
Personal Numerical Code (CNP)	text field	number (unsigned integer), 13 bytes, verification of errors based on algorithm *
Age	text field	number (unsigned integer), 3 bytes, numerical check – values should be between 0 and 115
Birth date (day/month/year)	date field	date (two digits.two digits. four digits), automatically extracted from CNP
Gender	radio button, coding: 1 – male, 2 – female	number (unsigned integer), 1 byte automatically extracted from CNP (the first digit in CNP is 1 or 5 or 7 for males and 2 or 6 or 8 for females)
Stable Residence:		
County code	combo box according to SIRUTA's county codes	number (unsigned integer), 2 bytes
Sector City code	combo box according to SIRUTA's sector city codes	number (unsigned integer), 1 byte
City code	combo box according to SIRUTA's city codes	number (unsigned integer), 6 bytes
Address (optional)	text field	text, 100 characters
Temporary Residence:		
County code	combo box according to SIRUTA's county codes	number (unsigned integer), 2 bytes
Sector City code	combo box according to SIRUTA's sector city codes	number (unsigned integer), 1 byte
City code	combo box according to SIRUTA's city codes	number (unsigned integer), 6 bytes
Address (optional)	text field	text, 100 characters
Reason for reporting	radio button, coding: 1 – new diagnosed case, 2 – new case, 3 – check up, 4 – diagnosis revision, 5 – death with/by diabetes	number (unsigned integer), 1 byte

Table 1. Continuation

Facts about diabetes:		
Date of debut:		
Probable date of debut (day/month/year)	date field	date (two digits.two digits. four digits)
Date of diabetes diagnostic (day/month/year)	date field	date (two digits.two digits. four digits) *
Exit from records:		
Exit records data (day/month/year)	date field	date (two digits.two digits. four digits) *
Reason to exit the records	radio button, coding: 1 – emigration, 2 – cured, 9 – death	number (unsigned integer), 1 byte *
Diabetes Type	radio button, coding: 1 - Insulin-dependent diabetes mellitus, 2 - Non-insulin-dependent diabetes mellitus, 3 - Other specified diabetes mellitus, 4 - Unspecified diabetes mellitus	number (unsigned integer), 1 byte
Diabetes Type (ICD 10 code)	text field	text (format: I/__/cc.c.), 9 characters
Somatometry data:		
Weight (cm)	text field	number (unsigned integer), 3 bytes
Height (cm)	text field	number (unsigned integer), 3 bytes
Waist (cm)	text field	number (unsigned integer), 3 bytes
Body Mass Index (kg/m^2)	label	number (unsigned real, one decimal), 3 bytes, automatically computed using formula (weight / (height)^2)
Family history:		
Diabetes Mellitus	check box	Boolean
Obesity	check box	Boolean
Physiological history:		
Number of births	text field	number (unsigned integer), 2 bytes
Number of births with macrosoma	text field	number (unsigned integer), 2 bytes *
Number of births with malformations	text field	number (unsigned integer), 2 bytes
Perinatal death toll	text field	number (unsigned integer), 2 bytes
Complications:		
Diabetic neuropathy (ICD 10$^{\#\#}$ code: .4+) :	check box	Boolean *
Amyotrophy	check box	Boolean
Autonomic neuropathy	check box	Boolean
Mononeuropathy	check box	Boolean
Polineuropathy	check box	Boolean
Diabetic angiopathy (ICD 10 code: .5):	check box	Boolean *
Peripheral arteriopathy	check box	Boolean
Ulcers	check box	Boolean
Cancer	check box	Boolean
Diabetic nephropathy (ICD 10 code: .2+):	check box	Boolean *
Diabetic nephropathy	check box	Boolean

Table 1. Continuation

Complications:		
Glomerulonephritis intracapilary	check box	Boolean
Kimmelstiel-Wilson syndrome	check box	Boolean
Diabetic retinopathy (ICD 10 code: .3+):	check box	Boolean *
Cataracts	check box	Boolean
Retinopathy	check box	Boolean
Diabetic coma (ICD 10 code: .0):	check box	Boolean *
Coma with or without ketoacidosis	check box	Boolean
Hyperosmolar coma	check box	Boolean
Hypoglycemic coma	check box	Boolean
Coma Hyperglycemia NOS	check box	Boolean
Diabetic ketoacidosis	check box	Boolean *
Ketoacidosis	check box	Boolean
Treatment:		
Diet	check box	Boolean *
Exercise	check box	Boolean *
Oral hypoglycemic agents	check box	Boolean *
Insulin	check box	Boolean *
Pancreas transplantation	check box	Boolean *
Metabolic control:		
Blood sugar (mg/dl)	text field	number (unsigned integer), 3 bytes*
Glycosuria	text field	number (unsigned integer), 3 bytes
Glycosylated hemoglobin (%)	text field	number (unsigned real, one decimal), 3 bytes *
Biological balance:		
Cholesterol (mg/dl)	text field	number (unsigned integer), 3 bytes
HDL Cholesterol (mg/dl)	text field	number (unsigned integer), 3 bytes
LDL Cholesterol (mg/dl)	text field	number (unsigned integer), 3 bytes
Triglycerides (mg/dl)	text field	number (unsigned integer), 3 bytes
Urea (mg/dl)	text field	number (unsigned integer), 3 bytes
Uric acid (mg/dl)	text field	number (unsigned integer), 3 bytes
Creatinine (mg/dl)	text field	number (unsigned integer), 3 bytes
Proteinuria (mg/mmol)	text field	Boolean
Associated Diseases:		
Hypertension	check box	Boolean
Abdominal obesity	check box, (true if the abdominal circumference is >=88 cm in women or if the abdominal circumference is >=102 cm in males)	Boolean
Peripheral arteriopathy	check box	Boolean
Dyslipidemia	check box	Boolean
Heart diseases	check box	Boolean

Table 1. Continuation

Patient education on diabetes:		
Medications	check box	Boolean *
Self monitoring of blood sugar level	check box	Boolean *
Diet	check box	Boolean *
Hypoglycemia	check box	Boolean *
Exercise	check box	Boolean *
Foot care	check box	Boolean *
Current data documentation:		
Comments	text field	text, 250 characters, optional
Physician First Name	text field	text, 30 characters
Physician Last Name	text field	text, 30 characters
Physician code	text field	text, 7 characters
Completion Day	label	date (two digits.two digits. four digits), filled automatically by the system
User	label	text, 70 characters, automatically filled according logging into the application

Legend: # - (Informatics System of Administrative – Territorial Units Registry) [ ], ## - International Classification of Diseases – the international standard diagnostic classification for epidemiological use, management and clinical use [ ], * - fields to be stored in the register.

2. If in the DRG data (source 3) on any of the final diagnosis codes there is a code for diabetes and there is no code in the database then a new record is inserted into the diabetes register. Data that can be transferred to the register are name, identification number (CNP – personal numerical code), type of diabetes, disease registration date. If the patient is already registered in the diabetes register then there will be no updating of the information because DRG data won't add anything new.

3. If there is data in the register, and data appears in Pharmacy files (source 4) only drug field will be taken into account from this data source. This information will be used for identifying the type of treatment. After identifying the types of treatment (oral agents or insulin), the code in theregistry will be updated.

4. If there is data from laboratories (source 5) and in two separate determinations for blood glucose values are exceeding 125 mg/dL, or blood sugar glucose tolerance test in two hours are exceeding 200 mg/dL, and there is no patient entry in the diabetes register, then patient identification data and other biological determinations will be add into the patient's diabetes registry.

5. For death bulletins (source 6) the data about death cause can be used in the registry.

D.2 Algorithm. removal of patients from the registry records

When the DIA forms (source 1), or when diabetes institutional records (source 2), have a record that shows: emigration, death, healing, or when death bulletins (source 6) records exist for a patient, that person is removed from the register of diabetes (marking out the stop of follow up).

The structure of data sources collected for the diabetes register

In Table 2 the electronic data sources, along with the type of information that they provide, and the degree of trust for the information are presented.

Table 2. Electronic data sources for the diabetes register. Information type and degree of trust

Data sources	Information type	Degree of trust
Form for reporting diabetes cases DIA	Identification data	High
	Data about diabetes	High
	Coding	High
	Completeness of cases for the form	High
	Completeness of cases for the database/register	High
	The date of the source document	High
Institutional register for diabetes	Identification data	High
	Data about diabetes	High
	Coding	Variable, different systems of disease coding
	Completeness of cases for the form	Depends on local practices
	Completeness of cases for the database/register	Depends on local practices
	The date of the source document	High
Institutional medical records databases	Identification data	High
	Data about diabetes	Depends on local practices
	Coding	Variable, different systems of disease coding
	Completeness of cases for the form	Depends on local practices
	Completeness of cases for the database/register	Depends on local practices
	The date of the source document	High
DRG (Diagnosis Related Group)	Identification data	High
	Data about diabetes	Moderate, doar pentru identificarea cazului
	Coding	High Alt sistem de codificare al bolilor
	Completeness of cases for the form	High
	Completeness of cases for the database/register	Poor
	The date of the source document	High
Pharmacy	Identification data	High
	Coding	Moderate/Poor
	Completeness of cases for the form	High
	Completeness of cases for the database/register	Poor
	The date of the source document	High
Laboratory	Identification data	Moderate
	Data about diabetes (lab data)	High
	Coding	Depends on local practices
	Completeness of cases for the form	Depends on local practices
	Completeness of cases for the database/register	Depends on local practices
	The date of the source document	High
Death statistical bulletin	Identification data	High
	Death date	High
	Document date	High

Discussion

The heterogen nature of the medical information sources that can be used to build a national diabetes database, and a national register of diabetes, asks for a unifying data system.

One approach to this is the possibility to export several of the presented medical information sources in a Microsoft Excel file format. These files can then be sent in an encrypted form to a national aggregating point, where data can be merged into the database. The Microsoft Excel file format has the advantage that Microsoft Office and Microsoft Windows operating system are the prevalent programs used in hospitals and almost all medical institutions. Also some of the medical information sources, already export their data in Microsoft Excel files, or have the option to export it in this format.

An important issue with this heterogen system to retrieve the information upon multiple data sources, is the need to uniquely identify each patient in the system. This is important to make sure we are following the same individuals in time, and that data do not duplicate, or mix.

In Romania each citizen is given a unique identifying number at birth, called Personal Numerical Code (CNP) [19]. This number is written in the birth certificate, and then, by the age of 14, in the Identity Card of all the citizens of Romania. This number is used in almost all databases dealing with medical data. The Personal Numerical Code, can then be used to correlate data from all these multiple medical sources. Due to the nature of this code, it can be used to check the accuracy of some data about the patient. The code stores, information about the sex of the subject, their birth date (year, month, day), and the county where the subject was born.

The approach to use multiple medical information sources pose some difficulties.

It requests that current medical information sources to be analyzed and means of exporting data in a suitable format to be generated. This process takes time, and can be expensive.

Also the current data sources may not provide all information of interest. Some of the applications that are in use allow customization and expanding of their current capabilities, in order to extend data gadering for diabetes information. This customization process takes time and also can be expensive, depending on the company that is maintaining the application. Where the data source is not sufficient for the purposes of the diabetes register, the online version of the DIA form can be used to surpass this inconvenient.

Conclusions

The paper presented the structure of a national diabetes database, and registry, and the medical sources of information that can provide data to a diabetes register, their degree of trust, algorithms for entering new diabetes cases, or removing cases from the register. When data is not available for current medical sources of information, a form with a specified structure can be used to add data to the register.

Conflict of Interest

The author(s) declare that they have no conflict of interest.

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