



HEALTH DATA ANALYSIS: MEASURING OUTCOMES AND QUALITY OF DIABETES CARE IN THE BLACK SEA REGION

S. PRUNA¹, A. BEALLE² and CONSTANTIN IONESCU-TIRGOVISTE³

¹Telemedica Consulting, Health Information Systems, Bucharest, Romania.

²Institute of Diabetes "N. Paulescu", Bucharest, Romania

Corresponding author: Simion PRUNA, E-mail: simion.pruna@gmail.com

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Designed to define common data items (parameters) for monitoring the targets of the St. Vincent Declaration by measuring the outcomes and quality in health care, the DIABCARE Basic Information Sheet (BIS) is the most known and used European dataset. This has been the basic tool of the approach of data comparison between diabetes centres related to primary care and to secondary care in diabetes. DIABCARE was created as the main tool for data collection both in hard copy (DIABCARE BIS form) and as Computer Program (DIABCARE Epi Info). Both tools have been used extensively across Europe over the last 20 years for the implementation of the St Vincent Declaration initiative. The DIABCARE dataset filled out by the doctors or medical nurses (by voluntary bases) working in diabetes in countries from Black Sea area allowed an exchange of information for monitoring, continuing diabetes care in comparative evaluations between diabetes centres in the region. In order to measure the outcomes and quality in diabetes care an overall 3,079 patients were included in this survey, 627 (20.4%) with type 1 and 2,428 (78.9%) with type 2 diabetes. About 24 (0.8%) had unknown type of diabetes. Most of the study participants were females 1838 (59.8%) and 1238 (40.2%) were men. The distribution of BMI categories among the patients revealed that 32.3% were classified as normal weight (BMI <25 kg/m²), 34.6% as overweight (BMI 25-30 kg/m²), 25.7% as obese (BMI equal and above 30 kg/m²) and 7.5% were not known or not measured. This paper addresses the targets of the St Vincent Declaration implementation in terms of measuring the outcomes and quality in diabetes care in Black Sea region.

Key words: St. Vincent Declaration, Black Sea Diab Union, DIABCARE, health data analysis, outcomes measurements, HbA1c.

INTRODUCTION

According to the World Health Organization (WHO) the prevalence of diabetes for all age-groups worldwide was estimated to be 2.8% in 2000 and 4.4% in 2030. The total number of people with diabetes is projected to rise from 171 million in 2000 to 366 million in 2030¹. However, this upper figure, although comprehensive in terms of prevalence, by definition it does not included people with undiagnosed diabetes². A 'true' measure of the process still cannot easily be derived because diagnostic criteria has a deep

impact on prevalence of gluco-metabolic abnormalities, even if data is effectively collected from multiple sources. Use of the consensus definition might decrease the number of missed cases. Diabetes screening in risk individuals is usually based on the conventional method (WHO 1999) by detection of hyperglycemia through an increase in fasting plasma glucose (FG ≥ 126 mg/dl) or 2-hour post-load glucose in the oral glucose tolerance test (2hPG ≥ 200 mg/dl). The American Diabetes Association (ADA) has authorized (2010) the use of the hemoglobin A1c (HbA1c) as diagnostic criteria for diabetes and other glucose

abnormalities ($\text{HbA1c} \geq 6.5\%$)^{3,4}. Therefore, the “ADA 2010 criteria” for diagnostic diabetes are: $\text{FG} \geq 126 \text{ mg/dl}$, $2\text{hPG} \geq 200 \text{ mg/dl}$ and $\text{HbA1c} \geq 6.5\%$ while “WHO 1999 criteria” are: $\text{FG} \geq 126 \text{ mg/dl}$ and $2\text{hPG} \geq 200 \text{ mg/dl}$.

Presently, the highest prevalence of type 2 diabetes mellitus (T2DM) is in Saudi Arabia making it an epidemic health hazard because the prevalence of metabolic syndrome in Saudi adults varies from 16% to 40% depending on the definition used and the study location⁵. Also, T2DM is very high in over 10% of adults in the USA, Switzerland and Austria. Prevalence is low in Norway, China and in Iceland⁶. The international scientific community is worried because the data-evidence from prospective studies shows that the incidence of childhood type 1 diabetes mellitus (T1DM) is increasing and the age of onset of diabetes is decreasing. In children aged 0–4 years, in whom there was an annual increase of 11% while the annual increase in those aged 5–9 was 4% and in those aged 10–14 was 1%⁷.

Diabetes healthcare burden

One of the most prevalent chronic diseases, with an increasing incidence in acute and chronic complications, diabetes presents a vast worldwide growing socioeconomic burden as investigated in a number of studies using top down methodology^{8,9}. According to the IDF Diabetes Atlas, (fifth edition (available here: <http://www.idf.org/diabetesatlas/5e/healthcare-expenditures>)) “the estimated global healthcare expenditures to treat diabetes and prevent complications totaled at least US dollars (USD) 465 billion in 2011. By 2030, this number is projected to exceed some USD 595 billion”. The estimates show that more than three-quarters of the global healthcare expenditure due to diabetes in 2011 are for people between the ages of 50 and 79 years¹⁰. For example, hyperglycemia in admitted patients is an indicator of poor outcomes, with increased length of stay and health care cost^{11,12}. Hypoglycemia is also common and is associated with increased need of emergency room visits and hospitalization and higher mortality¹³.

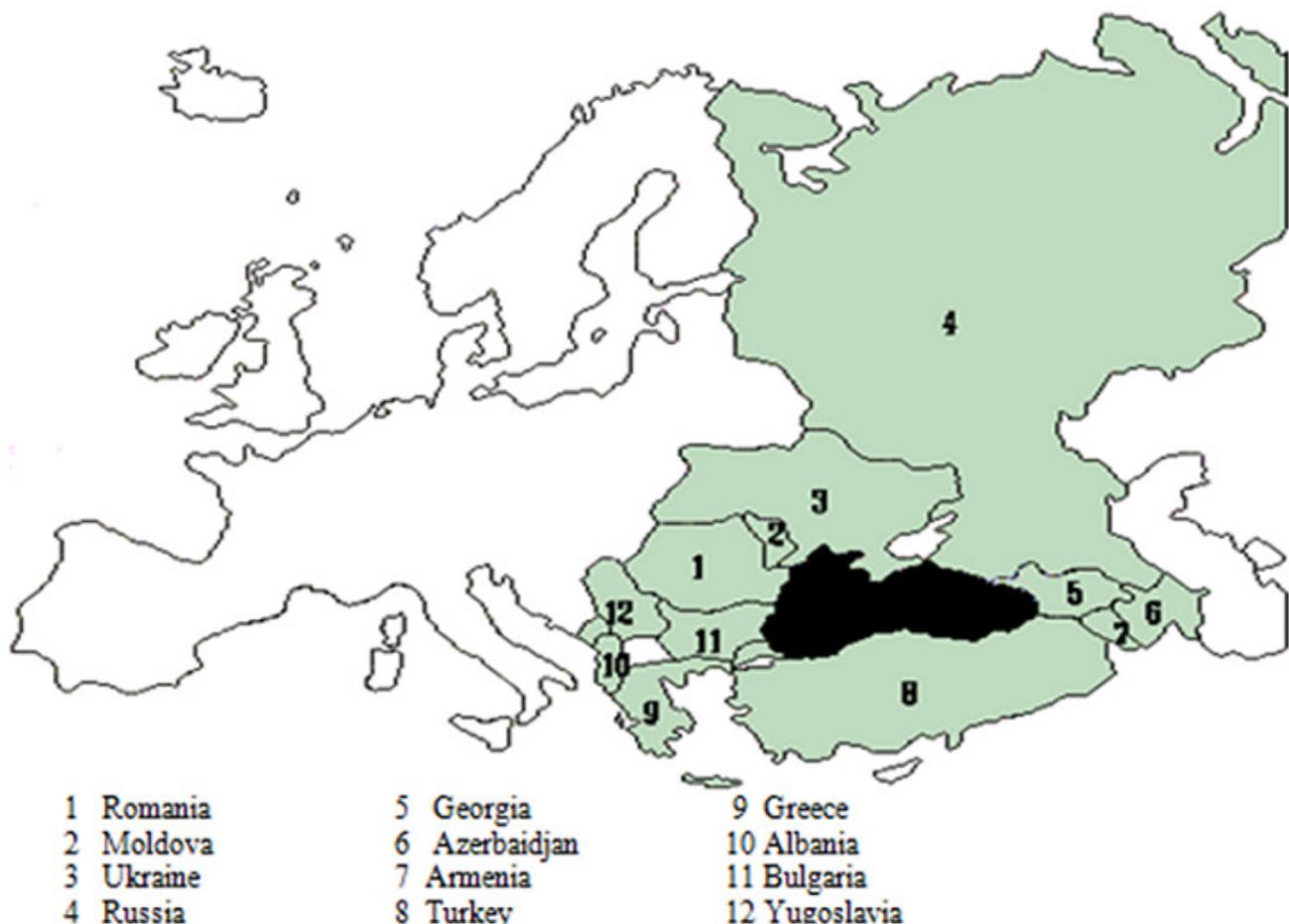


Fig. 1. Countries from Black Sea area participating in the BSDU.

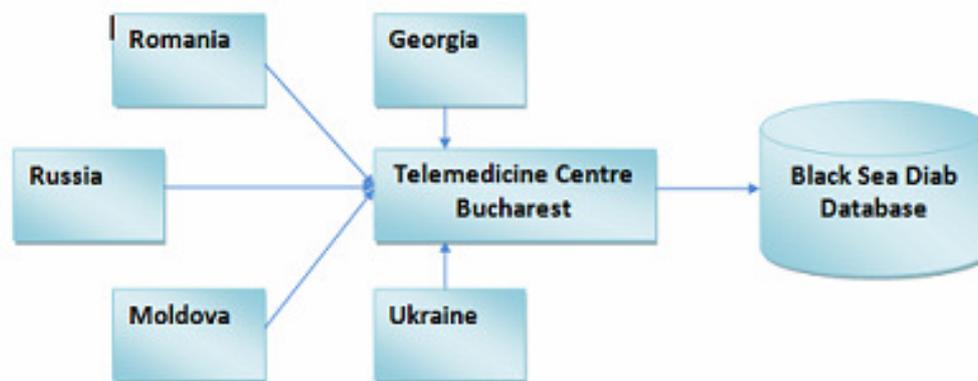


Fig. 2. Multicentric clinical data integration in Black Sea region.

Glycemic control a resolution on diabetes care

Nowadays, any improvement in glycoemic control is seen as a mean of preventing or slowing the progression of severe risks posed by diabetes and its complications (*e.g.* microvascular complications, with potential benefits in terms of reduction of the risk of kidney disease)¹⁴. Therefore, a primary objective of diabetes management is to improve glycoemic control¹⁵. Maintaining glycoemic levels as close to the non-diabetic range as possible has been demonstrated to have a powerful beneficial impact on diabetes specific complications, including nephropathy, retinopathy and neuropathy for both the T1DM and the T2DM^{16,17}. Increasing prevalence in many countries in terms of heart failure and diabetes, 1–2% of total health budget relates to heart failure and heart failure accounts for about 2% of all hospital admissions. Beta-cell secretion is absent in T1DM (plasma insulin secretion). Therefore, for euglycemia to be maintained we need three external artificial elements (outside of the human body): the sensor model, controller model and insulin pump model (discrete insulin delivery based on correlation with the level of glucose)^{18–20}.

HbA1c measures the amount of glucose that binds to hemoglobin over a period of 3 months. Therefore, in diabetes the HbA1c parameter (also called the glycated or glycosylated Hemoglobin) is the gold-standard measurement of chronic glycaemia. Annual change in baseline HbA1c in venous blood samples is recommended for early detection and follow-up of patients at risk of diabetes complications.

INITIATIVES TO MEASURING THE OUTCOMES AND QUALITY

The Declaration of St. Vincent – In order to support public health research efforts directed to the prevention and care of diabetes in Europe by

ensure continuous improvement in the quality of care and for the implementation of quality management in diabetes through modern technology, including data evidence-based approach, it was launched the St. Vincent Declaration (St. Vincent, Italy) in 1989²¹. This was a joint initiative on diabetes care and research of the World Health Organization (Europe) and the International Diabetes Federation (Europe)²². The St Vincent Declaration, was signed by representatives of diabetes associations, specialists in diabetes and experts who worked closely in the concrete implementation of public health programs for health services in diabetes, as well as representatives of European health ministers²³.

It is a strategic program per medium and long term designed to improve the quality of care provided to patients with diabetes in Europe by reducing chronic complications.

Common data set on diabetes

The lack of standardization of data definition was the essential drawback of the approach of routinely collection of hospital admission data at the beginning of 1990's decade for the measurement of the outcome indicators in diabetes services²⁴. Therefore, aiming to address this issue, the WHO/Europe (Quality of Health Systems) has initiated the development (through a formal consensus process) of a common diabetes dataset entitled, "DIABCARE". Fields and definitions of DIABCARE have been agreed to allow common monitoring of diabetes throughout Europe. DIABCARE dataset Basic Information Sheet (BIS) was also created to define a common data items (parameters) and indicators (target outcomes), as an instrument effective for comparing data collected from across different centers. Developed through a collaborative action between European countries, this BIS defines diabetes data as a common

Table 1

Detailed breakdown of number of patients for male and female among four countries

SEX * COUNTRY Crosstabulation

Count		COUNTRY				Total
		1	2	3	4	
SEX			3			3
	F	552	628	588	70	1838
	M	386	535	233	84	1238
Total		938	1166	821	154	3079

Table 2

Detailed breakdown of number of patients for type of diabetes and age category among four countries

AGE_CAT * COUNTRY Crosstabulation

Count		COUNTRY				Total
		1	2	3	4	
AGE_CAT	Type 1 17-25	33	62	12	47	154
	Type 1 25+	97	192	44	74	407
	Type 1 < 17	10	36	3	17	66
	Type 2 50-70	580	598	528	1	1707
	Type 2 70+	99	109	170	1	379
	Type 2 < 50	110	156	63	13	342
	Unknown	9	13	1	1	24
Total		938	1166	821	154	3079

Table 3

Detailed breakdown of number of patients for duration of diabetes among four countries

DUR_CAT * COUNTRY Crosstabulation

Count		COUNTRY				Total
		1	2	3	4	
DUR_CAT	0-4 years	248	471	279	63	1061
	05-9 years	160	204	165	37	566
	10-14 years	191	206	178	25	600
	15-19 years	145	134	108	13	400
	20-24 years	88	61	45	13	207
	25-29 years	52	37	26	2	117
	30+ years	36	32	19		87
	Unknown	18	21	1	1	41
Total		938	1166	821	154	3079

Table 4

Detailed breakdown of number of patients for BMI category among four countries

BMICAT * COUNTRY Crosstabulation

Count		COUNTRY				Total
		1	2	3	4	
BMICAT	BMI 25 - 30	392	395	246	31	1064
	BMI 30+	282	229	275	5	791
	BMI < 25	213	522	146	113	994
	Not Known	51	20	154	5	230
Total		938	1166	821	154	3079

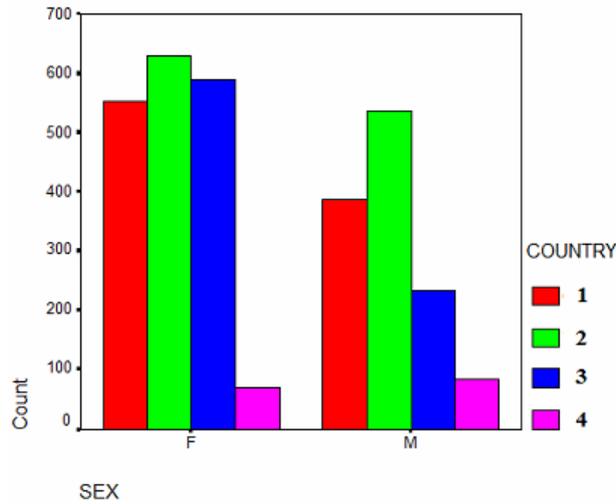


Fig. 3. Direct comparison of number of patients for male and female among four countries.

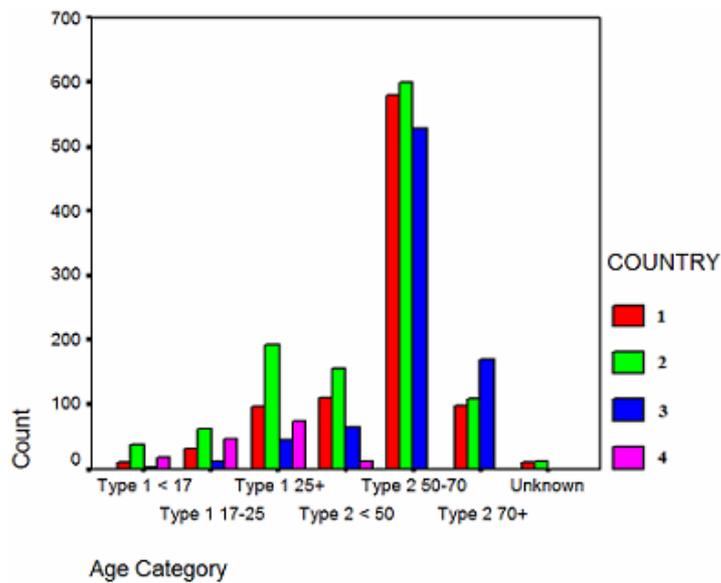


Fig. 4. Comparison of number of patients for type of diabetes and age band among four countries.

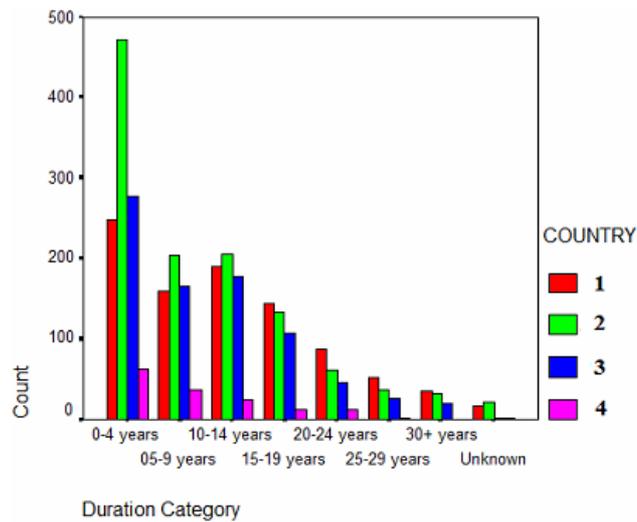


Fig. 5. Direct comparison of number of patients for duration of diabetes among four countries.

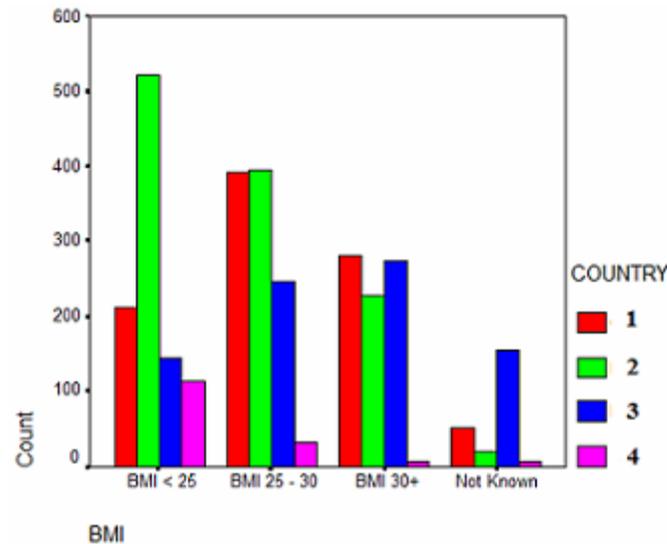


Fig. 6. Direct comparison of the distribution of BMI categories among four countries.

data set on diabetes which has been proposed to monitor diabetes mellitus and its complications in European countries²⁵. The tools for documentation of the quality of health status have been developed in three formats for use in different health care settings. These tools are:

- DiabCare Diabetes Dataset;
- DiabCare Basic Information Sheet (BIS);
- DiabCare Computer Program (DIABCARE Epi Info).

The WHO in Geneva in collaboration with the CDC in Atlanta designed Epi Info to collect data and to produce statistical analysis graphs, charts

and tables (as an alternative to the Fax/scanning solution²⁶). Epi Info allows data to be entered directly into a computer in a user-friendly manner. The computer interface looks like the BIS form and data are typed into the fields. Data were stored in the computer and sent to the collection centre over the Internet or on a diskette and through the mail system. All these tools were designed, developed and extensively implemented to allow local feedback-driven improvement in the quality of care. They were also the subject of communication protocols to compare performance between centres, regions, and countries²⁷.

Table 5

Detailed breakdowns of number of patients for HbA1c records among four countries

Count		COUNTRY				Total
		1	2	3	4	
HbA1c	HbA1c 10+	138	88	91	37	354
	HbA1c 8-10	23	107	62	29	221
	HbA1c < 8	49	131	47	18	245
	Not tested	728	840	621	70	2259
Total		938	1166	821	154	3079

Table 6

HbA1c done	Type of Diabetes			N (%)
	Type 1 (%)	Type 2 (%)	Other Type (%)	
Yes	3 (100.0)	97 (98.0)	0 (0.0)	100 (98.0)
No	0 (0.0)	2 (2.0)	0 (0.0)	2 (2.0)
TOTAL	3 (2.9)	99 (97.1)	0 (0.0)	102 (100.0)

HbA1c done * Type of Diabetes

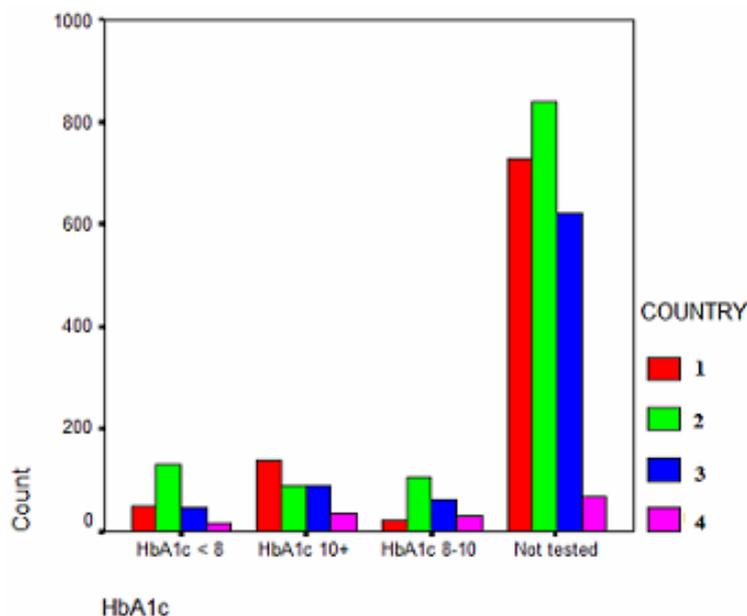


Fig. 7. Direct comparison histogram of HbA1c measurement distribution among the four countries.

The DIABCARE data set BIS has been structured that it is easily to register data on it, to enable consistent data capture (over 50 process and outcome variables related to the diabetes care can be collected) and subsequent analysis. There are quantitative data items (variables) based on measurements (*e.g.* HbA1c, BP, Creatinine, Microalbuminuria, etc. most recent value in the last 12 months) and qualitative items (*e.g.* smoking, alcohol, etc. based on answer Yes/No). The DIABCARE BIS data set form (a page A4 size) was designed to make the logical data separation as follows:

- Basic patient data (*e.g.* patient's initials first name and last name – to ensure anonymity outside of the clinic, DOB, type of diabetes, diabetes since, OAD since, Insulin since).
- Reason for consultation/admission (*e.g.* consultation or admission, routine visit, newly diagnosed).
- Pregnancies (*e.g.* ending with last 12 months, normal, abortions).
- Risk factors current status (*e.g.* Yes/No type data about Smoking status, alcohol).
- Self-monitoring (*e.g.* blood glucose/week).
- Education (*e.g.* Yes/No type data about healthy eating, foot care, complications).
- Measurements (*e.g.* Weight (kg), Height (cm), Blood pressure (mmHg), Blood glucose (mg/dl or mmol/l), HbA1c (%), Total cholesterol, HDL cholesterol).
- St. Vincent targets (*e.g.* Yes/No type data about blindness, MI, stroke).

- Symptoms (*e.g.* Yes/No type data about postural hypotension, peripheral neuropathy).
- Examinations (*e.g.* Yes/No type data about eyes examined last 12 months: retina seen, retinopathy and feet examined last 12 months: normal vibration sensitivity, foot pulses present, etc.).
- Quality of life/emergency (*e.g.* hypoglycaemia, hyperglycaemia, sick leave, hospital days).
- Management (*e.g.* Yes/No type data about diet only, biguanides, insulin injections/day, insulin-pump).
- Additional treatment (*e.g.* Yes/No type data about hypertension, cardiac failure, nephropathy, neuropathy).
- Name of physician (optionally), signature physician and date.

Law, ethics and governance

One of the major concerns when using a new technology is the issue of data security and confidentiality, especially when data contains a person's medical history. The EU has established a set of regulations that govern the storage and exchange of patients' medical records. To guarantee that only the appropriate health care personnel have access to patient records, the patient database has to be protected against unauthorized access and should keep access audit trail in accordance with the European Directive of Data Protection and regulations²⁸.

Black Sea Diab Union initiative

To achieve the recommendations of the St Vincent Declaration this initiative it was launched (by Prof. C. Ionescu-Tirgoviste) in 1995 as a consistent approach to collaborate among 12 countries in the Black Sea region for the management of diabetes. As part of the St. Vincent implementation strategy, the Black Sea Diab Union (BSDU) was launched under the umbrella of the WHO/Europe (Quality of Health Systems) with the occasion of the European Association for the Study of Diabetes (EASD) annual meeting held in Stockholm, Sweden, 12–16 September 1995²⁹.

The BSDU was created as a forum of the physicians and researchers working in the field of diabetes care aiming the achievement of St. Vincent declaration goals in the countries of the Black Sea area. The overall information technological aim of this project was to develop a communication infrastructure to monitor the ability to achieve the targets set out in the St. Vincent declaration. There was a need to develop a measurement mechanism for diabetes outcomes in region. There was also recognized a need for constant improvement of diabetes care and the harmonization of the standards of care of the Black Sea area. Therefore, aims and objectives of the BSDU were:

- To implement the aims of the St. Vincent Declaration in the Black Sea region countries.
- To unite the forces involved in diabetes care and research in the countries of the region.
- To create an avenue for the harmonization and improvement of care in the Black Sea area.
- To provide a forum for the publication of research results for health care workers from these countries.

It aimed to collaborate with governmental bodies as well as with non-governmental organizations in an effort to fulfill its goals. As part of the implementation of the St. Vincent declaration, the Quality of Care and Technologies (QCT) office of the WHO/Europe encouraged the formation of a group like BSDU to implement technologies capable of doing this.

This group of countries, illustrated in Figure 1, is a loose consortium of diabetes clinicians and informaticians from Romania, Bulgaria, Greece, Moldova, Russia, Turkey, Georgia, Armenia, Azerbaijan, Yugoslavia (at that time), Albania and Ukraine. In terms of the data collection, the diabetologists were in the front line of professionals by using the DIABCARE (BIS or Epi Info). They recognized and accepted the

implementation of this BSDU programme, due to their involvement in diabetic education and in the treatment of diabetes and its complications. The European dimension of the BSDU initiative, in terms of the geographical and scientific diabetes community recognition, is illustrated in the message written by the coordinator of BSDU, Prof. C. Ionescu-Tirgoviste, Bucharest, Romania, and published in the Vol. 3, Number 4 of the BSDU newsletter:

“As a result of our joint efforts and especially those of the team led by Temel Yilmaz, the First BlackSeaDiab Congress held in Istanbul in the fall of 1997 was a great success. As always, the WHO gave us substantial support through Kirsten Staehr-Johansen and Isuf Kalo. For the first time, the IDF was represented by two of its foremost figures - Philip Home and Massi Massimo-Benedetti. It can be said that the BlackSeaDiab “ship” already built, has now been fully commissioned to service. We all felt the pressure of the short time remaining till the end of the millennium. This is the reason why we organised the 23 Working Groups regarding the important aspects of modern diabetology”.

Data integration

As a first step in the project, centres were asked to use the BIS in the Diabetes clinics and to enter the information on a simple DiabCare Epi_Info 604 running in DOS database provided as part of the Quality Network by the WHO. To integrate data from various sources (national diabetes centres) into a data warehouse for a single unified view for the purpose of report generation in terms of quality of care, the anonymised data-files were emailed to the Black Sea Diab coordinating centre (Telemedicine Centre in Bucharest). After data analysis the reports were sent both to the WHO Europe in Copenhagen and to the centres who submitted data.

One advantage of being connected to the Internet was that we could send data files by e-mail. Therefore, the referral of a patient from a district to a national centre could take minutes rather than days through conventional surface mail. We have developed a simple package for the storage and transfer of medical information and health care data between district and national centres. The system has been implemented in five Romanian district centres. Nationally, it has been implemented to transfer data between national centres: Georgia, Moldova, Romania, Russia, Ukraine and Turkey.

In Black Sea area community, aggregated data from few countries were sent to a centralized processing centre (Telemedicine Centre, Bucharest) for analysis and reported. Diabetologists and nurses in the diabetes care units collected data by filling in BIS forms or feeding the data into personal computers.

The data collection service was initially organized through an E-mail network on a list of relevant university diabetes centers in Romania (Bucharest, Brasov, Braila, Buzau, Craiova, Constanta, Galati and Suceava) through data collected with DIABCARE Epi_Info. National language version of Epi Info for Diabetes was obtained from the St. Vincent Declaration Secretariat, WHO Europe. Medical staff involved into data collection attended a one day training course in Bucharest. We had well defined BSDU objectives that were specific, measurable and realistic to achieve within the resources committed, and achievable within a one year time frame:

- Patient's data were collected in Diabetes clinics using DIABCARE Basic Information Sheet;
- Data from the forms were entered into the WHO Diabetes Epi-Info database;
- The text data files were combined and compressed into a single ZIP file using a file compression utility;
- Details of the data files were written in a text file sent by email with the attached ZIP file to the national centre.
- At the national centre the attached ZIP files were decompressed to obtain the patient data file.
- The integrated data files from the Epi-Info databases were sent to the WHO Europe for benchmarking.

Starting with this pioneering work (in 1996) DIABCARE Epi_Info was the first software implemented in Romania (and Black Sea countries) to enable the storage and exchange of the WHO Europe Diabetes Aggregated Data (DAD) of patients with diabetes. The data were shared between Romanian diabetes centres and between diabetes centres of the Black Sea region.

BLACK SEA AREA CLINICAL DATA ANALYSIS IN COMPARATIVE EVALUATIONS

To our knowledge, this was the largest national multicentre, region wide survey to estimate prevalence rates of adequate versus inadequate

health management in Black Sea area, and the first to evaluate these rates in patients with diabetes.

The data and the results in this chapter are samples of real clinical data contained in the BSDU database. By measuring the outcomes and quality in comparative evaluations, they are not intended to be treated as data that truly represent the practice or efficacy of the diabetes care services from national centers of the countries in Black Sea region that submitted data. Clinical data analyses for diverse parameter (*e.g.* patient demographics, risk factors, intermediate outcomes) were conducted using commercial statistics software SPSS (SPSS Inc., Chicago, IL, version 9). For us, it was only available and capable software of performing statistical analysis in the health care studies and research, although, like many other commercial statistics software, they have high costs and require highly trained personnel.

Data were recorded at random from the point of care, coming directly from clinicians (during health care delivered) from diabetes clinics or hospitals in Georgia, Romania, Russia and Ukraine over period 1997–2000. Therefore, it is important to mention that through this data source, real clinical data were accessible.

Patients basic characteristics

The baseline characteristics of the patients (age, sex, type of diabetes, diabetes duration, and Body Mass Index) among participating countries are summarised in this chapter. They are presented as directly comparison among recruitment countries for various parameters. As format for presenting, data are shown both in table format and as histograms (standard benchmark graph). However, it should be noted that data only be allowed into the public domain in anonymised format, *e.g.* for each country it was assigned a number as country code (*i.e.* 1, 2, 3, and 4).

For the aim of this study overall 3,079 patients were included in this survey, 627 (20.4%) with type 1 and 2,428 (78.9%) with type 2 diabetes. 24 (0.8%) had unknown type of diabetes. Most of the study participants were females 1838 (59.8%) and 1238 (40.2%) were men. The distribution of BMI categories among the patients revealed that 32.3% were classified as normal weight (BMI <25 kg/m²), 34.6% as overweight (BMI 25-30 kg/m²), 25.7% as obese (BMI equal and above 30 kg/m²) and 7.5% were not known or not measured.

The detailed characteristics of the included patients are shown in Table 1 (for gender), Table 2

(for type of diabetes and age category), Table 3 (for duration of diabetes) and Table 4 (for Body Mass Index). Patient characteristics also are presented as histograms in figures 3, 4, 5 and 6 for gender, type of diabetes and age category, duration of diabetes and Body Mass Index, respectively. Regarding diabetes duration there was a large range of diabetes duration as is shown in Table 3 (duration category * country crosstabulation) and as a histogram in Figure 5.

Risk factor HbA1c assessment

The data presented were stratified anonymously by country (1, 2, 3 and 4). The HbA1c were stratified as "tested" and "Not tested". The values of HbA1c were also classified into three arbitrary categories: HbA1c < 8.0%, HbA1c between 8.0–10% and HbA1c ≥ 10.0%.

Tables 3–8 shows that the percentage of patients who missing the HbA1c test (at least annually) was significantly higher than the percentage of the patients who had HbA1c test: 77.6% vs. 22.4%, 72.0% vs. 28.0%, 75.6% vs. 24.4% and 45.6% vs. 54.4% for country 1, 2, 3 and 4, respectively.

Also, the frequency histogram clearly illustrates in Figure 7 that there was a lack of HbA1c measurement among BSDU countries, in spite it is a key indicator for assessing the quality of diabetes care.

DISCUSSION

Feasibility of comparability of the national indicators

The Black Sea Diab study has started in 1996 by annually gathered data aiming to assess the effectiveness in diabetes care by measuring the outcomes and the quality indicators. We used the Diabcare BIS and collected 3079 patients³⁰. Data were collected from clinics in 4 countries (Georgia, Romania, Russia and Ukraine) over period 1997 to 2000. By using the common data set DIABCARE to collect data, and e-mail approach for data transfer to an integration data centre for data analysis and report, we were able to understand the effectiveness of current healthcare practices in diabetes at level of few diabetes centres. We were able also, by using clinical data samples, to measure comparatively the outcomes and the quality in diabetes. In this study, we particularly aimed to investigate the risk factors level HbA1c in

care-based sample of patients with diabetes in region.

The problem addressed based on data as factual evidence was of strategic importance associated with the lowest risk factors targets in diabetes (*e.g.* HbA1c in T2DM). In the context of active and healthy ageing diabetes guidelines have been developed in terms of risk factors to improve the capability of health care organizations to address these issues. Risk prediction can be used as prognostic information and also as support for intervention. Data collection contributes to diabetes health care services in three important ways. First, measuring the outcomes and quality in diabetes is compatible with the objectives of the St. Vincent Declaration care and it is possible through collection and analysis of data in a common data set as it is DIABCARE. Second, the data allows for surveillance of specific issues such as sub-optimally used HbA1c test. Finally, diabetes registry data provides critical data for analysis to generate and disseminate health information used in public health by supporting policy-making through the systematic evaluation of different strategies for health care and prevention.

For the last 20 years we believed into the value of data analysis to assessment the quality of health care aiming to reduce diabetes complications. However, little of the analysis has been published or placed in the public domain. Results of data analysis were presented with various occasions of the BSDU meetings, as factual evidence of health care in Black Sea area³¹. They were perceived among the health care providers communities in region as something helpful had happened in our region for the patients with chronic diseases. Our results had the potential to make a significant public health impact and to generate and disseminate health information and knowledge both at regional and national level.

The potential impact through the dissemination and use of the data analysis results

The results of health data analysis of clinical data samples to measuring the outcomes and quality in diabetes care in Black Sea region (using data from hospitals or from diabetes clinics) show that HbA1c was sub-optimally used in the Black Sea area. The main causes of high number of patients missing HbA1c test could be the lack of equipment or the higher costs of HbA1c test than the glycaemia test. However, HbA(1c) is a parameter with serious diabetes-related

complications, a proven risk factor for the development of microvascular complications and poor quality of life in individuals with diabetes. The risk of MI or stroke, being fatal in T2DM, is associated with risk factors, including HbA(1c), measured many years before onset of MI or stroke³². In this trial the majority of patients were not tested and therefore, was not assessed the effect of the intervention (ongoing diabetes case management) on glycemic control using serial HbA(1c) measurements over several years. The pilot data analysis beside it has provided pertinent information about the decreased rate of HbA1c measurements it revealed also, the high level of values of HbA1c for the registered cases. The lack of HbA1c measurements on one hand and too high HbA1c on the other hand may contribute to an increasing risk for diabetes chronic complications and patients' mortality and morbidity.

The data evidence gained from the pilot data analysis about the sub-optimally used of HbA1c test provides a strong basis for the perspective of the preventive actions in terms of diabetes care. For policy makers there was a need to act reasonably quickly devoting financial efforts to move to wider glycemic control using the serial HbA(1c) measurements. Therefore, it had positive public health impact on this issue following dissemination of information based on our data evidence. The recent data analyses prove that in the last years, there has been an increasing interest in the role of the HbA1c test. The new status of the HbA1c, as an important test in diabetes in Romania, is demonstrated in Table 6. On a cohort of 102 new diabetes patients registered in a database in Institute "N. Paulescu" in Bucharest, only 2% have not been HbA1c tested. The data analysis was done with BIRO technology as it was described elsewhere³³.

The samples of clinical data received from several diabetes centers have been produced some meaningful analysis in Black Sea region as initiative for Quality Promotion and Epidemiology in Diabetes using Information systems (data collection based on DiabCare BIS and DIABCARE Epi-Info) followed by feedback and report by using commercial statistics software. Also, these results could be used to identify the areas of validity and of non-validity within the data to practical contribute of the results to health prevention in patients with T1DM and T2DM on body weight, the effect of blood glucose control on the biochemical parameters: HbA1c, lipids, etc.

The current state of knowledge in process of diabetes care, annual summaries with measurement of HbA1c test is the most common threshold for "poor glycemic control" at HbA1c \geq 9.5%. The therapeutic goal in the treatment of diabetes in terms of prevention of risk factors for complications, the predictors criteria are for maintaining HbA1c $<$ 6.5%³⁴. New diabetes regulations were issued in 2008 by Food and Drug Administration (FDA): "HbA1c remains an acceptable primary efficacy endpoint for approval of drugs seeking an indication to treat hyperglycemia secondary to DM"³⁵. Therefore, FDA adequately emphasizes the importance and necessity of HbA1c test as a key indicator for assessing the quality of diabetes care.

Strengths and limitations

The distinctive strengths of this study with the objective of investigating the feasibility of using routinely collected data at the level of clinical interaction (through horizontal data integration links) to assess diabetes care are the large multicentre sample and the collection of data by clinicians (health care providers in diabetes). Despite that, the main limitation is that it may not be representative of the whole population patients with diabetes of the participating countries in Black Sea area at the regional level (through vertical data integration links).

Due to relatively small number of cases gathered and analyzed, the impact of the BS integrated data on diabetes care was minimal. However, the data has provided pertinent information on the rate of diabetes complications and the risk factors for those complications. Limitations of the impact of the study is due to the fact it was based on voluntary bases participation of doctors to data collection by filling in BIS forms or feeding the data into PC using Epi Info. The greatest disadvantage of the data collection system described in this paper is the poor adherence to data collection leading to lack of continuity in data collection and therefore, leading to the lack of a prospective study for a longer period of time. In most cases, there is great resistance to voluntary data collection. The extra payment for data collection is a not a viable solution. Therefore, further work is seeking to find ways (based on the evolution of the ICT technologies) to solve these problems through data collection and data integration which is necessary in prevention of disease complications.

The results of clinical data analysis demonstrate that diabetes can cause chronic complications including sudden death, hyperglycaemia or hypoglycaemia, myocardial infarction, angina, heart failure, stroke, renal failure, peripheral vascular disease (resulting in the necessity for amputation), retinopathy, and blindness. Therefore, it is important to understand (based on data analysis) what clinical practices are effective in reducing the incidence of these complications^{36,37}. Unfortunately, diabetes disabilities reduce quality of life and result in enormous increasing direct and indirect medical costs. Therefore, more knowledge based on developing new ICT technologies for data-evidence for measuring the outcomes and quality is necessary in order to identify strategic areas of health care intervention for decreasing the diabetes healthcare costs: (i) Direct costs for patients admitted to hospital depending on length of stay, disease complexity, number of diagnostics and procedures per admission - inpatient, specialist visit and drugs. (ii) Indirect cost using a human-capital approach – premature mortality and productivity loss both due to sick leave by complications and long-standing disability.

CONCLUSIONS

The European dimension of the BSDU initiative is of strategic importance in the context of its contribution to generate and disseminate health information and knowledge and to enhance the role of data analysis as factual evidence of health care in diabetes. The study based on clinical data samples analysis to measuring the outcomes and quality in diabetes care in Black Sea region is contributing to the St. Vincent implementation strategy in Romania, Bulgaria, Greece, Moldova, Russia, Turkey, Georgia, Armenia, Azerbaijan, Yugoslavia, Albania and Ukraine.

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