

## INITIATIVES ACROSS EUROPE FOR MEASURING THE QUALITY IN DIABETES CARE

S. PRUNA<sup>1</sup> and CONSTANTIN IONESCU-TIRGOVISTE<sup>2</sup>

<sup>1</sup> Telemedica Consulting,

<sup>2</sup> National, Inst. of Diabetes, Nutrition and Metabolic Diseases, “N. Paulescu”, Bucharest, Romania  
*Corresponding author: C. IONESCU-TIRGOVISTE, E-mail: cit@paulescu.ro*

*Received December 20, 2013*

This paper is dedicated in memoriam to Dr. Kirsten Staher Johansen, Copenhagen, Denmark, head of the Quality of Health Systems WHO/Europe, who passed away in October 2013. Kirsten was a very good friend of many Romanian scientists (including authors) and clinicians. She attended many national scientific events in diabetes that took place in our country (Bucharest, Craiova, Cluj, Iasi, Oradea and Eforie, Constanta). She has promoted our country at the European level with many occasions (both in Diabetes and Obstetrics) and supported without reserves the launching of the Black Sea Diab Union initiative (described in this paper) under the WHO/Europe umbrella. We have been involved in much collaboration including The “DIABCARE” project based on a complete and integrated information technology system to monitor diabetes care, according to the gold standards of the St Vincent Declaration Action Program and The “OBStetrical Quality Indicators and Data collection (OBSQID)” project on a trans-European basis for continuous assessment of the outcomes in perinatal care aimed at ensuring all patients high quality, cost-effective care.

*Key words:* Diabetes, DIABCARE, St. Vincent, Dr. Kirsten Staher Johansen, Declaration.

### INTRODUCTION

In this paper, we discuss about initiatives across Europe for measuring the outcomes and quality in diabetes care in which we have been involved. We first discuss very promising initiative, “*The Declaration of St. Vincent*” an ambitious movement aiming to decrease the chronic diabetes complication by 1/3 for all categories of complications. WHO (Europe) brought in 1990s this very challenging initiative to diabetes care aiming to improve the efficacy of health care delivery by implementation of quality management in diabetes through modern technology.

This has resulted in development other initiatives: DIABCARE and Black Sea Diab Union (BSDU) initiatives and the Q-Net project which had precisely specified objectives to collect data for evaluation of quality in diabetes care.

#### **The Declaration of St. Vincent**

The Declaration of St. Vincent (Figure 1) is extremely relevant initiative and supporting action to

public health research efforts directed to the prevention and care of diabetes in Europe. It is a large federated collaborative scientific development action of multidisciplinary nature aiming to make major impact in diabetes care outcomes. It was launched in Italy in 1989 as a very promising coordination action at European level to ensure continuous improvement in the quality of care based on information flows and exchange to driving the performance of the diabetes care. New skills and innovation were required for the implementation of quality management in diabetes through modern technology and data evidence-based approach<sup>1</sup>.

Well-formulated and very professionally prepared, this was a joint initiative on diabetes care and research of the World Health Organization (Europe) and the International Diabetes Federation (Europe)<sup>2</sup>. The St Vincent Declaration, was signed by representatives of diabetes associations, specialists in diabetes and experts who work closely in the concrete implementation of public health programs for health services in diabetes, as well as representatives of European health ministers<sup>3</sup>.

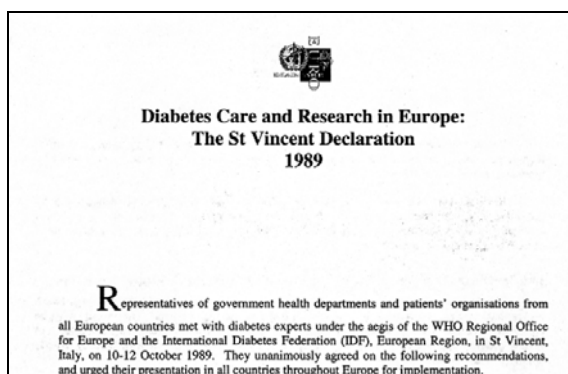


Figure 1. St. Vincent Declaration.

It was a strategic program per medium and long term designed to improve the quality of care provided to patients with diabetes in Europe with particular aim to reducing chronic complications by stronger competition between care providers. The principal areas covered are:

- Diabetes care and services.
- Diabetes complications.
- Early detection.
- Diabetes education, and
- Information systems.

### DIABCARE initiative

The DIABCARE initiative was a large multinational prospective study we have been involved. It was running under the umbrella of WHO/Europe (Quality of Health Systems) by adopting evidence-based benefits management approach to improve performance by prevention of diabetes complications in Europe.

Objectives of the action were analysis of current diabetes care by gathering national clinical data through DIABCARE dataset, identification of common success factors following data analysis and using findings and lessons learned to guide diabetes care providers to enhance the healthcare performances.

### DIABCARE Q-Net project

Initiated in Germany, the DIABCARE Q-Net project was part of the European Commission's Telematics Applications Programme aiming to improve quality in diabetes care and disease management<sup>4,6</sup>. The DIABCARE Monitoring Group of the St Vincent Declaration Steering Committee initiated this project as the first Telematics platform for standardized documentation on medical quality and evaluation across Europe<sup>5</sup>. This project has developed a complete and integrated information technology system, fully in line with the St. Vincent Declaration policy and its relevant outcomes. Q-Net project is very professionally developed and prepared to monitor diabetes care, through better information at all levels, aiming to identify programs and practices capable of diabetes care improving.

One crucial element to understand the background situation of diabetes care at national, regional or European level was building a high-quality and massive database about the outcomes and resource utilization in diabetes. Therefore, DIABCARE Q-Net has contributed to a wide spread and dissemination of the St. Vincent-Declaration initiative across Europe. As part of the technology innovation activities it is implementation of a pilot data gathering project for data analysis as factual evidence of health care. The main aiming is to improve diabetes care and disease management by the implementation of a quality network. The Q-Net project has implemented regional, national, and central nodes for processing of diabetes quality indicators based on standardized tools for quality improvement in diabetes care, i.e. the basic information sheet DIABCARE and by developing data entry and feedback software entitled "DIABCARE Data for Windows"<sup>6</sup>.

The Telemedicine Centre of "N. Paulescu" Institute, Bucharest, has contributed effectively to Q-Net database with anonymised patient data registered in DIABCARE Epi-Info. Data were collected by competent and experienced diabetologists from national centres in Black Sea area. DIABCARE BIS sheets were filled in hard copy and then in electronic records on disk by using the computer software (DIABCARE Epi-Info). Our competences were considered highly

valuable for partnership to the Q-Net project leading to new collaborations, improved training and professional development opportunities in terms of data collection and data analysis.

Resulting from the initiative of the St. Vincent-Declaration, the Q-Net project had the overall target of improvement the diabetes care by aggregation of anonymized patient data, evaluation, and feedback with the tools of modern telematics for the end of the 1990s decade. In terms of data analysis as factual evidence of health care in diabetes, the participating centers (GP's and clinics in Europe) to Q-Net project got feedback by standardized benchmarking.

The Fax/scanning is one of the technical solution necessary for data transmission between a local centre to Q-net central centre, implemented by Q-Net project. The "*Fax/scanning solution*" of data collection was based on filling out a sheet of paper (DIABCARE BIS). This paper could be sent as a fax or via normal mail. The Fax/scanning solution is a software capable of receiving and interpreting the data on the paper page. The computer programme identifies the form, extracts hand-written information from the form and inputs data from the form into a database.

As an alternative to the Fax/scanning solution was *Epi Info software* developed by the WHO (in Geneva) in collaboration with the CDC (in Atlanta, USA). Epi Info is designed to collect data and produce statistical analysis reports: graphs, charts and tables.

### **Black Sea Diab Union initiative**

The Black Sea Diab Union initiative is development of St. Vincent Declaration scenarios for Eastern Europe, particularly for countries in Black Sea region. The main relevant result of the Black Sea Diab Union (BSDU) initiative is that it has succeeded to gather real clinical data offering to health policymakers' pertinent information on the rate of diabetes complications and the risk factors for those complications. This means promoting the St. Vincent Declaration as a credible concept for measuring the quality of diabetes care. It also means democratizing the access to the tools and common datasets to anyone with the interest and willingness of starting new observational studies to assessment the quality of care.

Our Telemedicine Centre played the role as the central centre for data integration from national diabetes centres in Black Sea region. It belongs to the National Institute of Diabetes, Nutrition and

Metabolic Diseases "Prof. N. C. Paulescu", situated in Bucharest and performs basic and clinical research activities in the field of metabolic diseases. The major areas of interest are: neuro-electrophysiology, nutrition, genetics, epidemiology and immunology related to metabolic diseases. It is a university and research institute in diabetes, highly rated institution with a very strong scientific research base.

### **Strong forum of physicians and researchers**

To achieve the recommendations of the St Vincent Declaration, BSDU initiative was launched 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 BSDU was lunched 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 1995<sup>7</sup>.

The BSDU was created as a transnational strong forum of physicians and researchers working in the field of diabetes care by bringing them together to share data, knowledge and experiences 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 monitoring the ability to achieve the targets set out in the St. Vincent Declaration.

There was a need to develop a measurement mechanism for diabetes quality and 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 Black Sea area through a network of experts and researchers.
- To create an avenue for harmonization and standardization of diabetes care and expertise to be exploited for improvement of care in the Black Sea area.
- To provide an ambitious forum for the publication of research results produced by health care workers from these countries.

BSDU aimed to collaborate with governmental bodies as well as with non-governmental organiza-

tions in a clearly articulated 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. The methods used for the data collection were based on the diabetes DIABCARE Basic Information Sheet (BIS) developed by the WHO/Europe quality network.

This group of countries, illustrated in Figure 2, is a loose consortium of diabetes clinicians, researchers 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 and Epi Info.

They recognized the initiative importance and accepted to working voluntarily-based for the implementation of this BSDU programme, due to their involvement in diabetic education and in the treatment of diabetes and its complications.

Many BSDU meetings were organized (*e.g.* in Bucharest, Istanbul, Varna) to provide a strong basis for generate and disseminate knowledge on the latest scientific achievements and implementation of institutional public diabetes care knowledge for allowing the practical use of that knowledge on the diabetes field.

The BSDU conferences focus on the health implementation of St Vincent Declaration targets by reducing the impact of epidemic diabetes and chronic disease complications in Black Sea region. Researchers and clinicians reported on a whole variety of issues mostly concerning the understanding diabetes care issues and proposing common set of measures in translating this BSDU initiative into an action to combat disease complications as the key priority in the public health policy. The most relevant BSDU conference was the First Black Sea Diab Congress held in Istanbul in the fall of 1997. It was a great success in terms of international participating and scientific program, very relevant to the promoting of the best care process models in diabetes mellitus in our region.

#### **Dissemination to the diabetes community**

The BSDU initiative activities were disseminated through a regularly newsletter "*Black Sea Diab News*", distributed electronically and in hard copy, as is illustrated in Figure 3. All partners

in BSDU had opportunity to give their specific contributions to the newsletter for dissemination and promotion knowledge and results of activities and projects developed in connection with diabetes care. The newsletter was professionally prepared. The content includes the steps needed for dissemination of novel research data at BS level and for informal discussions and exchange of ideas for diabetes disease alert and response strategies. This publication had a positive public health impact on the health officials and healthcare workers in terms of promote health and health information by offering them update information to reduce the burden of diabetes in BS region.

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 BlackSea Diab “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*".

#### **Electronic health care registries**

Electronic Health Record (EHR) integrated with advanced data analysis can bridge the gap between the clinical care and the public health decision-making. This facilitates better performance measures for the benefit of patients care delivery and providing opportunities for administrative and clinical cost savings (*e.g.* eliminating duplicate lab tests). EHR is the key to the development, and ultimately the delivery of advanced data analysis solutions. All data surrounding the patient care registered by healthcare professionals in daily clinical life (*i.e.* valuable data and useful data) can be used for exchanging health information between clinicians across an organization that delivers patient care.

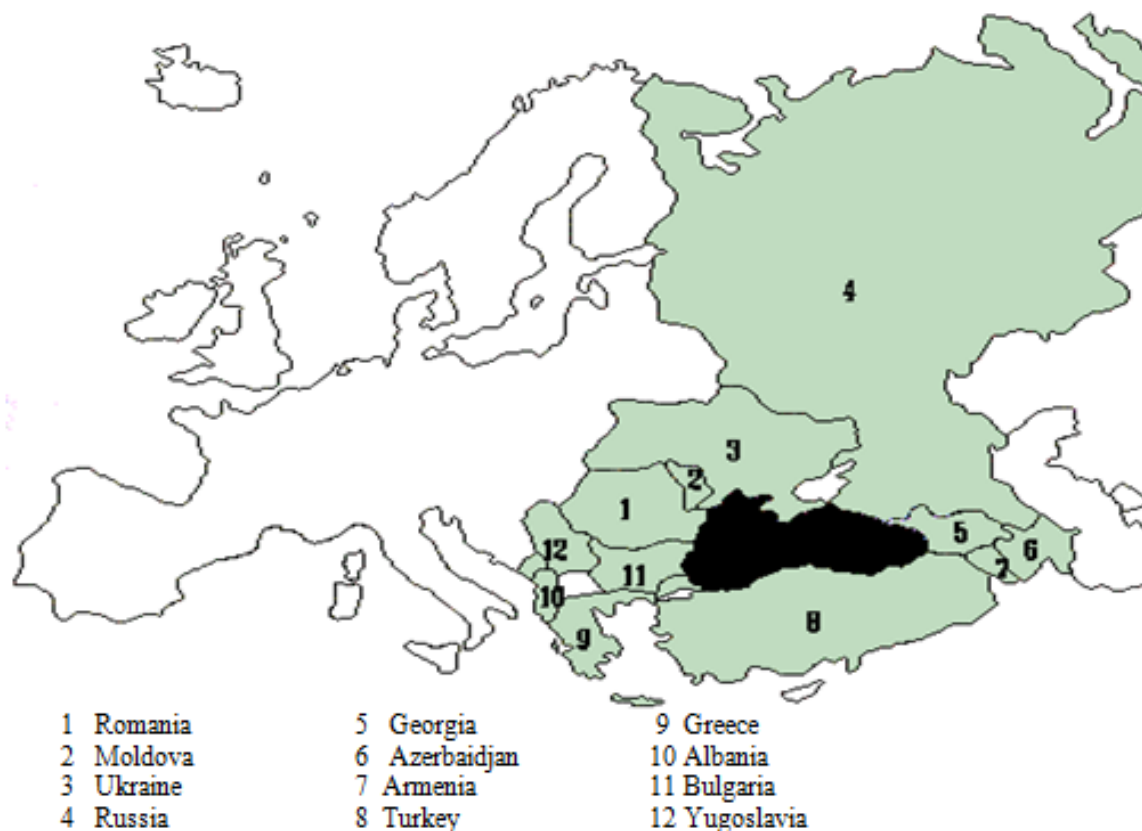


Figure 2. Countries from Black Sea area participating in the BSDU.

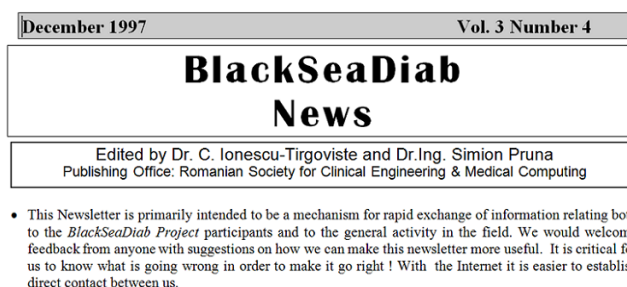


Figure 3. Black Sea Diab newsletter initiated and published by the author of this paper.

The first successful electronic medical record system was realized under the banner of the EU project “*Black Sea Tele Diab*” (BSTD)<sup>8</sup>, based upon standard *e.g.* the Good European Health Record (GEHR)<sup>9</sup> and the CEN ENV 13606<sup>10, 11</sup> on “Electronic Communications” and EU research projects *e.g.* Inco-Copernicus. 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<sup>12, 13, 14</sup>. The GEHR contains the set of concepts dealing with co-operation (patient records transfer) between healthcare providers around the care of a patient.

### What kind of challenges data collection faces

The lesson that had to teach us during St. Vincent and Black Sea Diab Union initiatives implementation is that voluntary-based data collection is not a self-sustainable solution. The quality and the quantity of data collection strongly depend on the motivation of the health care professionals and the time available to generate databases voluntarily. From the previous chapters we learned that there is no guarantee the adherence of healthcare professionals to data collection because they are too busy in daily professional activity to worry about the data collection for specific purposes of outcomes and quality measurements. That is

leading to lack of continuity in big databases gathering. That is leading also to missing a continuous process of audit / outcome monitoring of what happens in real clinical practice based on prospective / retrospective studies (independent of industry trials) for a longer period of time. The only way to successfully tackle these problems is by adopting electronic health care registries (EHR) through better access to data at the point of care. We need a more effective and more efficient approach for recording comprehensive and high quality data surrounded patient care than the voluntary-based approach. In other words, we need a “short cut” to quick and natural data collection and that is what EHR systems is all about.

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

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

However, in case of EHR systems, the most common causes of data integration problems are lack of data standardization. So, the main question raised was how an EHR system should be designed to address the systems interoperability to facilitate

big data integration in order to satisfy health data automatic analysis needs?

To address the above issues, at the foundation of the EHR systems we have developed and described in this chapter are the standard dataset DIABCARE, the papers charts used in diabetes care and the architecture of the Good European Health Record (GEHR) which provides a set of rules and principles for electronic registries and existing networks<sup>15</sup>. GEHR is a project within the Advanced Informatics in Medicine (AIM) program. The GEHR aims to develop and propagate a common architecture for computerized health records across Europe that can be used in clinical domains, countries, and computer systems<sup>12</sup>.

We think that this foundation (DIABCARE and GEHR) might be necessary also to be applied to modern digital technologies of the electronic health care registries systems like web-based resources and cloud computing.

### **WHO Europe review and clinical implementation**

According to the scientific/technical reviews of the WHO/Europe (Quality of Care and Technologies) and the DG XIII of European Commission, the BSTD project was very successfully finalised as an EHR system which allows developing and propagating a common architecture for computerised health records in diabetes across countries in Black Sea area.

Application of software and high speed communication technology in CCE/NIS countries had led to support of developing IT for health in Eastern Europe countries and in this way avoid widening the gap existing between East/West Europe. The project has led to create a prospective database similar to the existing database in the EU, enabling intensified epidemiological and clinical research of Diabetes in our region.

After the BSTD project was finalized and the EHR system was implemented as a diabetes register into clinical routine for data collection we had a visit of an expert in diabetes epidemiology from England (*Dr. Malcolm Roxburgh, QCT office, WHO Europe, Copenhagen*). The aim of that visit was a technical review of the BSTD implementation and in particular highlighting the scientific/technical achievements of the project, its contribution to the St. Vincent Declaration targets and its impact for improving diabetes care.

The scientific/technical review report has the following conclusions:



- The BSTD software project has succeeded in delivering a competent piece of diabetes clinic software, in step with emerging standards.

- The software is at a standard comparable with clinic IT systems marketed in Western Europe.

- There is a need to act reasonably quickly to move to wider implementation, and move beyond the scope of the research program.

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

By adherence of clinicians to the BSTD system the project consortium has proven the concept that it is possible to develop and use of a fully-computerised healthcare record system in a clinical setting. By implementation in many diabetes centres from Romania, Ukraine and Moldova BSTD was able to promote the use of electronic data exchange of healthcare information and to provide a framework for the epidemiological study and monitoring of diabetes care.

In addition, there are clinical protocols with treatment options that can significantly improve diabetes health care. Changes in procedural knowledge such as acquisition of decision rules can lead to more effective and efficient diagnostic and therapeutic strategies.

BSTD system has demonstrated to be a tool which can provide to clinicians a great advance in knowledge pertaining to etiology, diagnosis, treatment and management of a chronic disease such as diabetes. It is the main components needed to be integrated for measuring highly effective the outcomes and quality in a specific health care domain (e.g. diabetes) and making the data comparable over different countries.

### Summary

The paper describes the most important initiatives across Europe for the purposes of establishing a common understanding and common set of goals for improving diabetes care. The purpose of outcomes measurements is to take a step back so that we can explore what we really do, what our main strengths are, and where improvements could be made in our health care systems. They bring together representatives of

diabetes associations, specialists and policymakers in diabetes under the WHO Europe umbrella.

The main positive outcome in translating these initiatives into concrete action was the big data collection in diabetes care and data analysis related to the main European quality care indicators. Suitably anonymised, data analysis can help improve transparency in the public sector. Also, data analysis can provide reliable information to help health services managers and health policymakers to enhance performance in health care.

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 in our region. It was contributing to the implementation St. Vincent's strategy in Romania, Bulgaria, Greece, Moldova, Russia, Turkey, Georgia, Armenia, Azerbaijan, Yugoslavia, Albania and Ukraine.

### REFERENCES

1. Diabetes care and research in Europe: the Saint Vincent declaration. *Diabet Med* 1990, 7 (4), 360.
2. Attali, J. R., [DiabCare tools for the control of permanent improvement of the quality of care in diabetes]. *Diabete Metab* 1993, 19 (5 Suppl), 533-7.
3. Cathelineau, G., [Implementation of the Declaration of St. Vincent]. *Diabete Metab* 1994, 20 (3 Pt 2), 337-40.
4. Piwernetz, K.; Home, P. D.; Snorgaard, O.; Antsiferov, M.; Staehr-Johansen, K.; Krans, M., Monitoring the targets of the St Vincent Declaration and the implementation of quality management in diabetes care: the DIABCARE initiative. The DIABCARE Monitoring Group of the St Vincent Declaration Steering Committee. *Diabet Med* 1993, 10 (4), 371-7.
5. Piwernetz, K., DIABCARE Quality Network in Europe--a model for quality management in chronic diseases. *Int Clin Psychopharmacol* 2001, 16 Suppl 3, S5-13.
6. Gerlach, K.; Kaeding, A.; Kottmair, S.; Westphal, D.; Henning, G.; Piwernetz, K., The implementation of a quality-net as a part of the European project DIABCARE Q-Net. *IEEE Trans Inf Technol Biomed* 1998, 2 (2), 98-104.
7. Diabetes, E. A. f. t. S. o., Abstracts of the ... EASD annual meeting: Stockholm, Sweden, 12-16 September 1995. Springer: 1995.
8. Harris, N. D.; Raptis, A.; Raptis, S.; Dixon, R. M.; Grubb, P. A.; Ionescu-Tirgoviste, C.; Khalangot, N.; Anestiadi, V.; Anestiadi, Z.; Georgescu, M.; Stanciu, E.; Pruna, S., Black Sea tele-diab: development and implementation of an electronic patient record for patients with diabetes. *Health Informatics Journal*, ISSN: 1460-4582, OCLC Number: 440894190 2001, 7 (2).
9. Kalra, D.; Lloyd, D.; Austin, T.; O'Connor, A.; Patterson, D.; Ingram, D., Information architecture for a federated health record server. *Stud Health Technol Inform* 2002, 87, 47-71.

10. Blobel, B., Comparing concepts for electronic health record architectures. *Stud Health Technol Inform* 2002, 90, 209-14.
11. Blobel, B., Authorisation and access control for electronic health record systems. *Int J Med Inform* 2004, 73 (3), 251-7.
12. Pruna, S.; Dixon, R.; Harris, N. D., Black Sea TeleDiab: diabetes computer system with communication technology for Black Sea region. *IEEE Trans Inf Technol Biomed* 1998, 2 (3), 193-6.
13. Pruna, S.; Harris, N. D.; Dixon, R.; Laxminarayan, S., Black Sea Tele Diab: Building an Information System for Management of Diabetes. In *IEEE EMBS International Conference on Information Technology Applications in Biomedicine*, IEEE: Arlington, VA, USA, 2000; pp 284-289, ISBN: 078036449X.
14. Pruna, S.; Georgescu, M.; Stanciu, E.; Dixon, R. M.; Harris, N. D. In *The Black Sea Tele-Diab System: development-implementation-clinical evaluation*, Studies in health technology and informatics.; Medical informatics Europe; Medical infobahn for Europe proceedings of MIE2000 and GMDS2000,; Hannover, Germany, IOS Press: Hannover, Germany, 2000; pp 656-662, ISSN: 0926-9630.
15. Griffith, S. M.; Kalra, D.; Lloyd, D. S.; Ingram, D., A portable communicative architecture for electronic healthcare records: the Good European Healthcare Record project (Aim project A2014). *Medinfo* 1995, 8 Pt 1, 223-6.