

Establishment of a Romanian database and biological sample collection for antenatal research

Abstract

Objective. The aim of this paper is to make known our experience in developing the first data base and the biological sample collection for research in the area of antenatal medicine in our country and to identify interested partners in exploiting and developing it. **Methods.** Software of structured documentation in the area of antenatal medicine has been adapted by inserting fields in order to store data related to the acquired biological samples by integrating the clinical and para-clinical data with that in the sample collection. There were long distance tests made for multicentric use within a virtual private network (VPN). **Results.** Data from 11055 gravidas has been stored in the integrated data system with the physiological and pathological evolution and 5698 biological samples (serum, placenta amniotic liquid). The frozen samples and data are used for teaching and scientific purposes, for graduation and PhD thesis and interdisciplinary networking. **Conclusions.** The research platform that has been developed is the first one in this area in our country and it offers support for developing integrated research at European level. Multicentric and interdisciplinary use of this platform allows data collection on rare cases, precious in making progress in knowing and clarifying physiological and pathological phenomena during pregnancy. There is both a national and international interest in the development of these results.

Keywords: antenatal medicine, research, data base, biological samples.

Introduction

In practicing medical research, quick access to information, storing capacity, managing and selecting information according to various criteria is mandatory for efficient management⁽¹⁾. The evidence before implementing Information Technology showed that documentation for medical data only in written form creates difficulties in using it because it takes a long time to analyze it. Developing the structured documentation concept with the consensus of specialists offers the perspective of developing certain efficient informatics systems for the purpose of quality care control and research^(2,3).

Medical information that accompanies patients who register for antenatal medical care is very rich and significant, but it is often lost and unused. On the other hand, analyzing certain epidemiological phenomena or pathologic mechanisms is only possible by taking into consideration a significant number of cases that occur quite rarely. In the absence of a structured integrated system, these cases could pass undetected.

Explaining the mechanisms that contribute to a physiological or pathological evolution of some patients is found in the information that accompanies each patient and within the biological parameters from the biological samples that have been harvested. For this precise reason, there are many research centers that developed the concept of organizing a data

base and a collection of biological samples associated with it. Developing and using the offered facilities of such a concept could significantly contribute to obtaining additional knowledge in that specific area by analyzing 'data mining'⁽⁴⁾. Such an example is the Collaborative Transplantation Study, one that includes data and biological samples of over 500.000 transplanted patients⁽⁵⁾. There are also specific registries and data bases for certain pathological groups in obstetrics and gynecology⁽⁶⁾.

Research in antenatal medicine can be significantly improved by organizing a documentation system of cases (data base) and of preserved samples associated with them. But there are also some specifics of antenatal medicine, such as the inter-relationship between the gravida and the conception product which leads to the concept of materno-fetal binomial and the necessity of documenting data both from the gravida and the conception product. In addition, in order to use the information efficiently, the data needs to be stored according to the gestation age based on a system that allows dating according to the last period, ultra-sound or manual parameters. This feature allows temporal orientation of events during pregnancy. Associating this data base of a collection of biological samples (serums, plasma, amniotic liquid or tissues) allows a deeper studying or corroborating serological and clinical parameters. Exploring these will significantly contribute

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to knowledge development in the area of antenatal medicine^(7,8).

Methods

Adapting an integrated software system in antenatal medicine

In order to organize a data base with information and images, the ASTRAIA software (Astraia GmbH Munich, Germany) has been used, software especially designed for antenatal medicine⁽⁹⁾. It has been adapted by inserting new fields for data documentation regarding samples harvested from both gravidas and fetuses. The inserted sample fields were allocated to check-up within the data base, so that for each sample the patient, the pregnancy episode, the date and the time of collection can be automatically identified.

Testing and optimizing long distance usage in virtual private network

The intranet initially used system (within the establishment) was tested in order to use it in a multicentric setting in a virtual private network (VPN)⁽¹⁰⁾. The parameters of processing within a VPN network is sure and fast, similar to using an intranet within one establishment.

Patients group

The data base and the biological sample collection has been developed by gathering data from gravidas who came to Dr. Dumitru Popescu Obstetrics-Gynecology Clinic in Timisoara during 2006-2011. There was different types of information collected regarding demographics, heredity collateral antecedents, physiological and pathological antecedents, ultra-sound data, weight, laboratory analysis, pregnancy evolution and the new born. The gravidas and the new-born babies had a certain physiological and pathological evolution. There were serums collections, placenta fragments and amniotic liquid from various ages of the pregnancy. The samples were frozen at -80C.

Results

Data base and the collection of biological samples

There were ultra-sound images collected, demographical data, heredity collateral antecedents, personal obstetrical and pathological antecedents, ultra-sound and laboratory data, information regarding pregnancy evolution and of the new-born babies from 11055 gravidas. There were 5698 samples collected from 4243 gravidas. The samples were harvested during the first trimester at the gestational age of 5-8 weeks, 11-13 weeks and during the second trimester at 15-19 weeks. There was amniotic liquid collected at the moment of amniocentesis diagnosis and placenta fragments at the moment of abortion or birth. The samples were frozen at -80C.

Applications within the audit and quality control activities

There have been work procedures and queries developed in order to audit the medical activity and the analysis of quality indicators and also for the research purpose. The developed system allows the user to easily edit queries for the fields selected by the manufacturer or the newly inserted ones. Thus, there were queries performed, that factor certain subtle indicators, some that are extremely specific for the quality of the medical act: pH in the umbilical cord, Apgar score, neo-natal procedures, new-born baby's weight, etc. Enquires can be made taking into consideration other parameters, they are exportable and can be transmitted long distance, and allow to be easily reported and compared to other establishments in a centralized manner. The analysis that can be made with the aid of this developed system is highly flexible allowing unified multicenter queries within a few seconds.

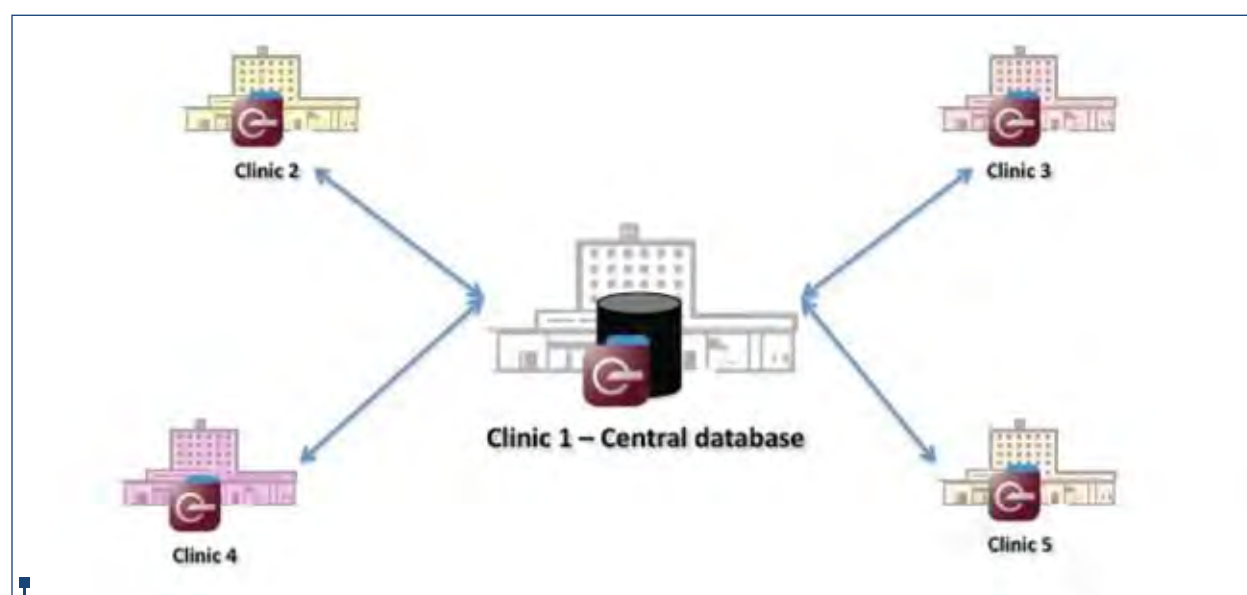


Figure 1. The layout of multicentric connection to the data base with the virtual private network (VPN). Many users form different locations connect through a secure Internet network in the public area to the central data base that manages the sample collection

Developing the system in order to access it in distance mode

In order to standardize documentation in different centers, there is the possibility of accessing the system long distance (Figure 1). Testing shows that the system can be used as VPN, the opening of the software being done in an inverse ratio interval with the access speed of the Internet network, so that within the same establishment the opening of the program happens in 20 seconds with Internet access of upload/download speed of 5 Mb/s. within 60 seconds and on Internet mobile devices at a speed of 1 Mb/s. upload/download in approximately 150 seconds⁽¹⁰⁾.

Research use. Published studies.

Studies on this data base were on assessing premature birth risk⁽¹¹⁾, the antenatal screening program for malformations in the 1st and 2nd trimester^(12,13) and assessing infection prevalence with materno-fetal transmission on the gravidas who came to the hospital⁽¹⁴⁾. Other specific subjects are regarding certain biometric factors (Body Mass Index) para-clinical factors (glycaemia, hemoglobin, etc.) on pregnancy evolution and that of the new-born. There were internal and international collaborations established in order to assess certain prognostic factors and pregnancy complications.

Discussion

Using an integrated system for data storing regarding collected biological samples represents a significant support for developing care quality control activities and scientific developments in the area of antenatal medicine⁽¹⁵⁾. Implementing similar projects within other specialties and other Universities had beneficial effects upon scientific activities' results and knowledge progress⁽⁵⁾. In order to collect long distance data, these systems can be adapted to be managed long distance through the Internet network⁽¹⁶⁾. Such multicentric systems are also functional in the area of obstetrics and gynecology^(17,18).

The large amounts of data about patients and their medical condition and evolution, which are harvested in the electronic databases, contain important information.

The information could be processed by data mining techniques to investigate the factors associated with care quality and obstetrical risk factors¹ or to discover new risk factors for pathology associated diseases.

The capacity of using this integrated system in a long distance network allows not only the analysis of a great number of cases, but also a cumulation of rare cases that one establishment cannot identify on its own, not having enough cases for research. Developing Internet communication techniques ensures the implementation of such applications for data bases and their analysis. Collecting biological samples and data regarding patients with different pathologies is also in the interest of big research laboratories in order to develop common projects.

By corroborating data about gravidas with the results of different parameters identified and analyzed within the harvested samples, there is important information that could be obtained regarding physiological and physiopathological mechanisms during pregnancy evolution. The data can be useful both for the patient and from a socio-economical point of view, being relevant even for the coordinators of public health systems.

Conclusions and perspectives

The establishment of a database and a biological sample collection is very important for the development of a research institution in the field of antenatal medicine and gives us the opportunity to develop further research projects. The experience of other worldwide research centers supports our approach. It is of high national and international interest to use the information and probes in a multicentric and interdisciplinary way. We look forward to be in touch with other research groups and study new topics in the field of antenatal medicine research. ■

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