

Multicentric collaborative database in obstetrics and gynecology. Interdisciplinary Multicentric Working Group on Antenatal Research

Dan Navolan^{1*},
Simona
Vladareanu^{2*},
Roland Denk³,
Mihaela
Craciunescu⁴,
Christian
Kleist⁵,
Adrian Ratiu¹,
Imad Lahdou⁵,
Diana Badiu⁶,
Marius Craina¹,
Ioan Sas¹,
Ioana Ciohat¹,
Tony Hangan⁶,
Ovidiu Nicodin⁷,
Bogdan
Panaite⁷,
Dorin Grigoras¹,
Crangu
Ionescu⁸,
Nicolae
Bacalbasa⁹,
Mircea
Onofriescu¹⁰,
Radu
Vladareanu¹¹,
Dragos
Nemescu¹⁰

1. Department
of Obstetrics-Gynecology
and Neonatology,
"Victor Babes" University
of Medicine and Pharmacy,
Romania

2. Department
of Neonatology,
"Carol Davila" University
of Medicine and Pharmacy,
Elias University Hospital,
Romania

Abstract

Notwithstanding the type of study that is planned (retrospective or prospective), a multicentric and interdisciplinary approach assures a much better progress of the data collection than a single center approach does. We present herein the potential applicability of the system adapted by us in the national projects budgeted by the Romanian Academy of Medical Sciences. In our research we use an adapted version of Astraia - a database for women's health data management. The database allows the documentation of main medical data about pregnant women, birth and neonates. The database was adapted to allow documentation of information about the biological samples collected and stored from patients. Queries were edited to allow identification and recognition of samples in the database. Our previous research recommends our platform for use in the following projects of the Romanian Academy of Medical Sciences: National Registry of Malformations and New Strategies in Health Prevention Measures.

Keywords: medical database, pregnancy, birth, neonates

Introduction

Notwithstanding the type of study that is planned, a multicentric and interdisciplinary approach assures a much better progress of the data collection than a single center approach does. This is because a multicentric approach allows a faster registration of patients in the study and assures a much heterogeneous study population than in a single center.

Running a multicentric project implies various difficulties, because data must be collected in accordance with a procedure and the distance between the centers may decrease the homogeneity of the data collection. Also running an audit is more complex in a multicentric than in a single center study⁽¹⁾.

In order for the benefits to exceed the disadvantages, the management team running a multicentric study needs an informatics tool to accurately manage the data about patients⁽¹⁾. For these reasons many software solutions were used and presented in the literature and proved to be more efficient than paper-based documentation⁽²⁻⁴⁾.

Specifically in antenatal medicine the data and images collected in the studies need not only to be accessible remotely, but also need to be ordered according to the gestational age⁽⁵⁾.

In this particular case of studies, an accurate determination of gestational age must be done based on first trimester ultrasound⁽⁶⁾. This is why the software used for the data collection must enable the determination of gestational age according not only to the date of last menstruation, but also to ultrasound measurements: crown-rump length of the embryo in the first trimester or biparietal diameter, femur length and transverse diameter of cerebellum in the second trimester, etc.

The documentation of the ultrasound images also represents an advantage because in the case of a study audit, the ultrasound images could be rapidly reviewed to verify the ultrasound measurements or documented disease.

Since we previously showed our first attempts to develop a multicentric database for antenatal medicine research⁽⁵⁾, we present herein the medical data that we can collect in our database and the perspective of extending our database in the field of gynecological research.

We also notice herein the applicability of the system adapted by us to the following projects of the Romanian Academy of Medical Sciences: National Registry of Malformations and New Strategies in Health Prevention Measures.

Methods

Strategies to interconnect databases in the network

There are basically two strategies to interconnect databases in the research network.

The first strategy was previously described and involves the storage of data and images on a single central database⁽⁵⁾.

The advantage of this approach is that the data are instantaneously updated. The main disadvantages are related to the speed and reliability of the internet connection.

If discontinuities in internet services occur, the transfer of images could be incomplete and the examination must be repeated by the physician. Such an incident could influence negatively the workflow in the investigation room.

The second strategy to database interconnection assures only the instant transfer of data to the central database while the ultrasound images and volumes are saved at a database located at each terminal.

The update of the image database on the central server could be done later during the night via the internet connection.

The advantage of this manner of documentation is that the workflow in each center is not disturbed by failures of the internet connectivity while the main disadvantage consists in the discontinuous data update.

Software solution

In our research we use an adapted version of Astraia, a Database for women's health.

Astraia is a software permanently updated with the newest results from the research of the Fetal Medicine Foundation in London and other experts. Astraia software allows very facile and user-friendly changes of screen configuration and insertion of new fields in order to store relevant data for the studies. Such changes were performed by us to insert a field dedicated to the identification of numbers assigned to each biological specimen that was collected from the patient during the study.

On the basis of the identification number inserted in the field we assure a reliable identification of the patient, date, and gestational age when the sample was collected.

Database interrogation facility and export of data

Our database management software allows a very friendly interrogation of the data.

The interrogation could be build up on the basis of a selection of the fields of interest on the screens or by building up queries in SQL language.

The interrogation of data could be performed including some conditioning criteria like interval of time, values, etc.

The system allows an interrogation in the central database and the export of the data in excels format or the interrogation of the local databases according to a certain query and the cumulating of the exported data.

Results

Medical data about the pregnant women registered in the antenatal medicine database

The antenatal medicine module of the database offers the possibility to save data in the following windows (each window represents a separate chapter): demographic data, history (i.e. obstetric history, chronic disease, family history, maternal medication during pregnancy), examination, ultrasound examination, and procedures (i.e. chorionic villus sampling, amniocentesis, cordocentesis, amniodrenaige or amnioinfusion).

Assessment of the pregnant women including values of the blood pressure and weight, weight gain during pregnancy, results of the blood investigations (i.e. maternal blood, maternal urine, karyotype, etc.).

The ultrasound examination allows the determination of the age of pregnancy according to the last menstrual period or ultrasound data (i.e. Crown-rump-length, cerebellum, biparietal diameter, etc.).

The ultrasound data are structured into the following chapters: early pregnancy, first trimester (including the measurement and algorithm for risk calculation according to the fetal medicine foundation), growth scan, fetal anatomy/biometry, Doppler examination and assessment of the cervical length.

All the values of the measured parameters are framed into nomograms.

Medical data about the birth and neonates registered in the antenatal medicine database

The main data about the birth and the neonate registered in the module of antenatal medicine comprise information about: the outcome of the pregnancy (i.e. life birth, intrauterine demise, termination, neonatal death, etc.), the name of the neonate, date of birth, gestational age at birth, mode of delivery, weight and length of the neonate at birth, Apgar Score, arterial and venous pH, labor onset, length of labor, presence of preterm rupture of membranes, pregnancy complications, complications in the neonatal period (i.e. ventilation, phototherapy, intraventricular hemorrhage, enterocolitis, blood transfusion) or congenital abnormalities.

Data about patients in the gynecology database

The main data registered in the gynecology module of the database are: details of the patient, history (i.e. obstetrical history, medication and family history), clinical examination, ultrasound examination, procedures, investigation results and outcome (i.e. date of decision to treat, date of the operation, operation type), histological findings. The ultrasound examination is structured in early pregnancy documentation, documentation of the uterus, ovaries, pelvic assessment, free fluid, adnexal masses, follicle tracking, and kidneys/bladder. The procedures chapter allows the documentation of the requested investigations, laparoscopy, laparotomy, hysteroscopy, and investigations results.

Discussion

The software proposed by us offers a support for data collection in multicentric studies in the field of

3. Astraia GmbH, Munich, Germany
4. Department of Microbiology, "Victor Babes" University of Medicine and Pharmacy Timisoara, Romania
5. Department of Transplantation-Immunology, Institute of Immunology, University of Heidelberg, Germany
6. Faculty of Medicine, "Ovidius" University of Constanta, Romania
7. Department of Gynecology, "Carol Davila" University of Medicine and Pharmacy, Central Military University Emergency Hospital "Dr. Carol Davila", Bucharest, Romania
8. "Carol Davila" University of Medicine and Pharmacy, Department of Obstetrics and Gynecology, "St. Pantelimon" Clinical Emergency Hospital, Bucharest, Romania
9. "Carol Davila" University of Medicine and Pharmacy, Bucharest, Romania
10. Department of Obstetrics & Gynecology, "Gr.T.Popa" University of Medicine and Pharmacy Iasi, Romania
11. Department of Obstetrics and Gynecology, "Carol Davila" University of Medicine and Pharmacy, Elias University Hospital, Romania

* Both authors contributed equally to this article.

Correspondence:
Dr. Dan Navolan
e-mail: navolan@yahoo.com

Received:
November 20, 2015
Revised:
December 18, 2015
Accepted:
January 13, 2016

obstetrics-gynecology and is superior to other software products because it is adapted to the particularities of materno-fetal medicine. The data are assigned to the pregnant women according to the gestational age and could be exported and statistically analyzed in a very easy and friendly way⁽⁵⁾. The network system presented by us is an efficient tool that could be used in a multi-centric way to collect data in studies and to participate

to research projects such as the programs funded by the Romanian Academy of Medical Sciences^(6,7).

Conclusions

We recommend our system as a reliable tool to be used in the projects entitled Romanian Registry of Congenital Malformations and Searching of New Strategies to Reduce the Prevalence of Preterm Birth in Romania. ■

References

1. El-Hayes K, Harrity C, Abu Zeineh T. A novel management database in obstetrics and gynaecology to introduce the electronic healthcare record and improve the clinical audit process. *Stud Health Technol Inform* 2006, 121, 266-75.
2. Peng TC, Van Dorsten JP, Dilzer P, Perry C, Ozcan G, Adams K, Dunn LJ. An integrated, hospital information system based obstetrical medical record and database. *Proc Annu Symp Comput Appl Med Care* 1991, 598-602.
3. Zandieh SO, Yoon-Flannery K, Kuperman GJ, Langsam DJ, Hyman D, Kaushal R. Challenges to EHR implementation in electronic- versus paper-based office practices. *J Gen Intern Med* 2008, 23(6), 755-61.
4. Kukafka RI, Ancker JS, Chan C, Chelico J, Khan S, Mortoti S, Natarajan K, Presley K, Stephens K. Redesigning electronic health record systems to support public health. *J Biomed Inform* 2007, 40(4), 398-409.
5. Navolan D, Ciohat I, Dragoi V, Constantinescu S, Badiu D, Timar R. et al. Establishment of a Romanian database and biological sample collection for antenatal research. *Gineco.eu*. 2013, 9, 80-2.
6. Kalish RB, Chervenak F. Sonographic Determination of Gestational Age. *TMJ* 2009, 59(2), 202-8.
7. <http://www.adsm.ro/ro/proiecte+europene+si+nationale/proiecte+nationale>. last visited on 23.12.2015.